

***United States Court of Appeals
for the Second Circuit***



**RESPONDENT'S
BRIEF**

77-4097

IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

Nos. 77-4097
77-4104

NATIONAL NUTRITIONAL FOODS ASSOCIATION, ET AL.,
Petitioners,

v.

FOOD AND DRUG ADMINISTRATION, ET AL.,
Respondents.

MILES H. ROBINSON, PRO SE,
Petitioner,

v.

FOOD AND DRUG ADMINISTRATION, ET AL.,
Respondents.

PETITION FOR REVIEW

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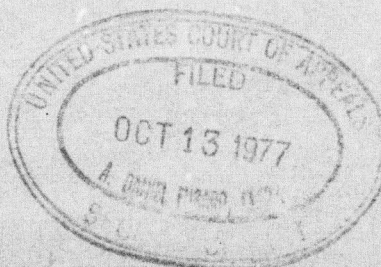


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IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

THE NATIONAL NUTRITIONAL FOODS ASSOCIATION,)
THE NATIONAL ASSOCIATION OF PHARMACEUTICAL)
MANUFACTURERS, and SOLGAR CO., INC.,)

Petitioners,)

v.)

No. 77-4097

DONALD KENNEDY, Commissioner of Food and)
Drugs, and UNITED STATES DEPARTMENT OF)
HEALTH, EDUCATION, AND WELFARE, FOOD AND)
DRUG ADMINISTRATION,)

Respondents.)

MILES H. ROBINSON, M.D.,)

Petitioner,)

v.)

No. 77-4104

DONALD KENNEDY, Commissioner of Food and)
Drugs, and UNITED STATES DEPARTMENT OF)
HEALTH, EDUCATION, AND WELFARE, FOOD AND)
DRUG ADMINISTRATION,)

Respondents)

BRIEF FOR RESPONDENTS
AND ADDENDUM THERETO

COUNTERSTATEMENT OF THE ISSUES

1. Whether the Food and Drug Administration complied with the remand instructions of this Court in National Nutritional Foods Association v. Food and Drug Administration, 504 F.2d 761 (2d Cir. 1974)?
2. Whether the Food and Drug Administration complied with Section 553 of Title 5 of the United States Code in amending regulations promulgated under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.) that were inconsistent with the 1976 Vitamin and Mineral Amendments (Pub. L. 94-278, Title V, April 22, 1976)?
3. Whether the Food and Drug Administration complied with the requirements of the 1976 Vitamin and Mineral Amendments in amending the Foods for Special Dietary Use regulations in 21 CFR §§ 105.3, 105.60, 105.77, and 105.85?

COUNTERSTATEMENT OF THE CASE

This is a consolidated petition for review of final regulations promulgated by the United States Food and Drug Administration (FDA) governing the labeling and composition of vitamin and mineral supplements sold as foods. The regulations at issue are published in Title 21 of the Code of Federal Regulations, Part 105, Sections 105.3, 105.60, 105.77 and 105.85.^{1/}

^{1/} The final regulations were promulgated as amendments to 21 CFR §§ 125.1, 125.2, 125.3 and 80.1 (41 F.R. 46170-46176 (October 19, 1976) and 42 F.R. 20292-20296 (April 19, 1977)), having been tentatively amended (40 F.R. 23244-23250 (May 28, 1975)) as part of a general Agency reorganization and republication (42 F.R. 14328-14329, 14331-14334 (March 15, 1977)). The Federal Register documents of May 28, 1975, October 19, 1976 and April 19, 1977 are reproduced in the Addendum to this brief. For convenient reference by the Court in reading this brief, citations to a section number of the regulations will be made to the Code of Federal Regulations (1977), followed in parenthesis by the corresponding section number and Addendum page and column in the pre-reorganization and republication notices.

The regulatory process began fifteen years ago with a Notice of Proposal to Revise Regulations, 27 F.R. 5815 (June 20, 1962). Extensive revisions in the proposed regulations were made by FDA in response to comments submitted by the affected industry and the public. An evidentiary hearing was held that lasted more than twenty two months and developed a transcript of 32,405 pages, together with hundreds of exhibits and other materials. On January 19, 1973, FDA published its proposed findings and conclusions and tentative version of the regulations for a final round of exceptions and comments (38 F.R. 2143). Final regulations were published in the Federal Register of August 12, 1973 (38 F.R. 20708, 20730), preceded by a lengthy preamble in which the Commissioner responded to each of the comments and exceptions submitted in response to the January 19, 1973 notice.

The regulations established definitions and standards of identity for dietary supplements of vitamins and minerals which permitted five basic types of preparations (a multivitamin and multimineral supplement, a multivitamin supplement, a multimineral supplement, a multivitamin supplement with iron, and a supplement consisting of any single vitamin or mineral) and specified certain mandatory and optional vitamins and minerals for inclusion in multnutrient supplements. The regulations also prescribed maximum and minimum potencies for ingredients in dietary supplements. These potencies were stated in terms of a new unit of measure, the "U.S. Recommended Daily Allowances" (U.S. RDA's) which were derived by the FDA from the Recommended Dietary Allowances (RDA's) published by the Food and

Nutrition Board of the National Academy of Sciences/National Research Council (the Board). In general, the minimum potency for a nutrient in a dietary supplement was established at 50 percent of the U.S. RDA for that nutrient; the maximum potency, at 150 percent of the U.S. RDA.

Subsequently, fifteen petitions for review were filed in various United States Courts of Appeals, and eventually consolidated in this Court. After extensive briefing and oral argument, the Court on August 15, 1974, held that it was "broadly sustaining the regulations", but it remanded the regulations to the Agency for certain further actions, National Nutritional Foods Association v. Food and Drug Administration, 504 F.2d 761, 786 (2d Cir. 1974).

The industry petitioners filed a petition for certiorari. The petition for certiorari was denied on February 24, 1975 (420 U.S. at 946).

Thereafter, FDA began the process of implementing the remand instructions of this Court. On May 28, 1975, FDA published a preliminary Notice in the Federal Register (40 F.R. 23244)^{2/} inviting applications for additional formulation dietary supplements, proposing certain other revisions in the regulations consistent with the Court's opinion, and announcing the reopening of the administrative hearing.

In the original hearing, the Hearing Examiner declined to permit Dr. Miles H. Robinson to cross examine Dr. William H. Sebrell, Jr., who had been chairman of the Committee on Recommended Dietary Allowances (the Committee) of the Board, concerning the process by which the RDA's were developed. This Court remanded the case to the Agency with instructions to reopen the record "for the limited purpose of permitting reasonable cross-examination of Dr. Sebrell (or, if he is not available, some other qualified member of the Board) by Dr. Robinson ..." (504 F.2d at 799).

^{2/} This Federal Register document is reproduced in its entirety in the Addendum to this brief (Ad., pp 1-7).

In a Notice of Reopened Hearing, published in the Federal Register of September 30, 1975 (40 F.R. 44857), FDA announced that Dr. Alfred E. Harper, Dr. Sebrell's successor as Chairman of the Committee would be available to:

respond to inquiry by those opposed to the regulations, concerning: (a) the methodology employed in the development of the recommended dietary allowances by the Board and the scientific foundation upon which these allowances are based, (b) the scientific appropriateness of Food and Drug Administration use of the Board's recommended dietary allowances, and (c) possible biases or conflicts of interest on the part of the Board, as well as any other subjects deemed by the Administrative Law Judge to be relevant to the examination mandated by the Court of Appeals.

The reopened hearing was held at FDA headquarters in Rockville, Maryland, in November, 1975 and lasted six days. Dr. Robinson took a leading role in the cross examination of Dr. Harper. An additional 1,120 pages of transcript were developed.

On February 20, 1976, the Administrative Law Judge (ALJ) entered his report and recommended order. His "ultimate findings of fact and order" were as follows:

(1) Alleged biases and/or conflicts of interest of the witness or other members of the Food and Nutrition Board have not been established in any degree which might reasonably be interpreted as affecting the judgment of the witness or other members of the Board in determining the RDA's.

(2) Although the Board determined the RDA's as a guide to sound nutrition for a healthy population, and not as standards for regulatory purposes, there is nothing inconsistent or unsound in using the RDA's as a basis for regulatory determinations as to labeling and nutritional content requirements, and

(3) Information adduced through detailed cross-examination into the scientific basis and methodology utilized by the Board in determining the RDA's does not require adoption of regulations differing from those published. (FDA Docket No. 75N-0107)

Exceptions to the report and recommended order were filed by the hearing participants.

While FDA was in the process of revising the vitamin and mineral regulations pursuant to this Court's instructions, Congress enacted new legislation (Pub. L. 94-278, Title V, April 22, 1976) restricting FDA's authority to limit the maximum potency of vitamins and minerals and inclusion of ingredients in dietary supplements which are offered for use by adults (other than pregnant or lactating women) and are recognized as safe. The 1976 Vitamin and Mineral Amendments became Section 411 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350) (the Act).

On October 19, 1976, FDA issued final regulations that complied with the 1976 Vitamin and Mineral Amendments as well as this Court's directions. The Commissioner discussed in a detailed fifteen page preamble the applications for additional formulations of dietary supplements, the exceptions filed in response to the report and recommended order of the Administrative Law Judge, the comments submitted in response to the May 28, 1975 tentative amendments to the regulations, and the effect of the vitamin and mineral legislation on the regulations (Ad., pp. 8-22). He announced his conclusion that the examination of Dr. Harper at the reopened hearing gave no cause for revision of the regulations and that he accepted the report and recommended order of the Administrative Law Judge without change (Ad., p. 10, 2d column).

The regulations now at issue are challenged by only two petitions from interested parties who participated in the 1974 appeal before this Court and who sought reconsideration of the October 19, 1976 order from FDA. One petition for reconsideration was submitted by Miles H. Robinson, M.D. "for himself, Federation of Homemakers, National Health Federation," and other named individuals, stating that they "cannot agree" with FDA's judgment that the cross examination of the witness at the reopened administrative hearing did not "impugn the U.S. RDA's" (See Ad. p. 29, 3d column). The other petition was submitted by the National Nutritional Foods Association, the National Association of Pharmaceutical Manufacturers, and the Solgar Co., Inc., (NNFA), asking that the Commissioner reconsider the procedural propriety of amending the regulations to comply with

the law without first issuing a proposal providing opportunity for a formal administrative hearing.

In the Federal Register of April 19, 1977, FDA responded to these petitions and made certain changes in the regulations. ^{3/} The notice concluded:

The Commissioner believes that there is no valid pretext for further litigation over the propriety of these regulations. However, if any of the petitioners for reconsideration believes that the new regulations fail to comply with the remand directions of the Court of Appeals as controlled by the new requirements of Congress, the Commissioner asks that any such person seek relief from the United States Court of Appeals for the Second Circuit forthwith so that the matter can be resolved as quickly as possible. The regulation of dietary supplements has been a matter of controversy for 14 years, with almost constant activity and uncertainty in the administrative, judicial and legislative arenas. There is need now for certainty and finality in the rules that govern this subject. (Ad., p. 33, 2d column)

This appeal followed. By order dated June 29, 1977, the two petitions were consolidated.

SUMMARY OF ARGUMENT

The regulations at issue have already been "broadly sustained" by this Court. FDA has faithfully complied with the Court's remand directions, and it has properly implemented the 1976 Vitamin and Mineral Amendments to the Act. As demonstrated below, there is ample scientific basis in the record to support the Commissioner's findings and actions in promulgating these regulations. Moreover, the evidence in the record does not support Dr. Robinson's allegations of bias and prejudice on the part of the witness or the ALJ. Finally, by no stretch of the imagination has FDA acted "hastily" ^{4/} in the promulgation of these regulations. But it has acted in accordance with the law.

^{3/} This Federal Register document is reproduced in its entirety in the Addendum to this brief. (Ad., pp. 29-33).

^{4/} As petitioners NNFA suggest on p. 48 of their brief.

The Argument which follows responds to the major points raised by petitioners' briefs.

ARGUMENT

I. The Scientific Basis For The RDA's Is Adequately Supported By The Administrative Record Compiled At The Reopened Hearing.

Dr. Miles Robinson is a pro se petitioner who believes that the RDA's established by the Board, from which FDA's U.S. RDA's are derived, are too low. He attributes the low RDA's to a conspiracy of the food, drug and medical industries, "each of which benefits greatly from food of low nutrient density. The food industry has high profits from 'junk' food which is cheap to produce. The drug, medical and surgical enterprises thrive on the diseases of malnutrition" (Brief, pp. 23-24). He accuses the Board and its chairman of having been bought off by the food industry (Brief, p. 18). He attempts to demonstrate the Board's bias (which resulted from being bought off by the food industry in furtherance of the conspiracy) by accusing it of using the wrong criterion for establishing RDA's, trying to set RDA's at the level found in the food supply, and using incompetent statistical methodology and nutritional data for animals which omitted "critical" information.

1. There Is Nothing In The Record To Support The Allegation That Dr. Harper And The Board Were Biased In Favor Of The Food Industry So As To Affect The Levels At Which They Set The RDA's.

Dr. Robinson went to great effort during the reopened hearing to uncover bias on the part of Dr. Harper and the Board in favor of the food industry that would have caused them to set the RDA's at what he considers to be a low level. The record shows that he was unable to do so.^{5/} Indeed, the government submits

^{5/} Citations to pertinent portions of the Transcript of the Reopened Hearing (Tr.) are found in the Addendum, p. 10, 3d column.

that an examination of the entire hearing transcript discloses that his argument with respect to Dr. Harper (Brief pp. 8-18) is without merit and based on speculation. Dr. Harper has received scholarships, awards, research support, and consulting fees from a variety of food companies. It is only logical that the food industry would provide scholarships, awards, and research grants for nutritional scientists and use their services as consultants. But Dr. Robinson does not agree. From these facts he concludes that Dr. Harper is biased, biased not because of any specific evidence, but biased because of appearances. He assumes, axiomatically, that if the Board and its chairman "are beholden to the food industry for money or other favors . . . that would tend to warp their scientific judgment with respect to healthful levels of the RDA's" (Brief, p. 15).

A considerable portion of Dr. Robinson's argument is an attempt to support this false axiom. For example, he alleges that Dr. Harper has "benefited from substantial funds from General Foods" (Brief, p. 11), making it sound as if Dr. Harper might have been a pauper without the financial favors of the food industry. Dr. Robinson notes that Dr. Harper held the General Foods professorship at the Massachusetts Institute of Technology (MIT) (Brief, pp. 11-12, 17), but he fails to acknowledge other facts brought out at the hearing and cited by the Commissioner (Ad., p. 10, 3d column) that do not fit his theory. Dr. Harper was a tenured professor at MIT and would have received his salary whether or not General Foods provided a grant to the university (Tr. 32523); Dr. Harper was appointed a Professor of Nutrition at MIT before MIT had received any support from General Foods (Tr. 32524); after Dr. Harper left MIT in 1965, the grant continued to be funded for that faculty position until 1975 (Tr. 32525). Furthermore, in suggesting that the transfer of the General Foods grant from MIT to the University of Wisconsin where Dr. Harper was Chairman of the Department of Nutritional Sciences "may have been a reward" for testifying at the reopened hearing, Dr. Robinson failed to mention the fact that Dr. Harper has no control over the

research being funded by the grant (Tr. 32527) and that the money is controlled by another professor who holds the chair (Tr. 32527-8).

Another example of the alleged bias of Dr. Harper is Dr. Robinson's theory of the so-called "Searle-Aspartame connection." Dr. Robinson takes three separate facts: (1) Dr. Harper has been a consultant to the Searle Drug Company on amino acids; (2) one amino acid, aspartic acid, is a major ingredient of the artificial sweetener, Aspartame; and (3) General Foods is interested in using Aspartame in its products and built an Aspartame plant for Searle (Brief, p. 10). From these three disparate facts Dr. Robinson concludes Dr. Harper's "ties to the food industry, especially through the Searle-Aspartame connection, placed General Foods and other food processors in a position to exert considerable influence on Dr. Harper to get the kind of RDA's most congenial to their business operations" (Brief, p. 16).

The Commissioner pointed out (Ad., p. 11, 1st column) that there is nothing in the record to support this view. On the contrary, the record indicates that Searle has little, if any, interest in the RDA's (Tr. 32502, 32503, 32507, 32509, 32513). No evidence in the record supports Dr. Robinson's contention that there is any connection between General Foods and Searle involving any significant interest in dietary allowances for vitamins and minerals.

Finally on this subject, Dr. Robinson asserts that a telegram sent to Senator William Proxmire by Dr. Harper challenging the accuracy of a speech by the Senator relating to FDA's demonstrated bias. Dr. Robinson further claims that during cross examination Dr. Harper retracted the views expressed in the telegram (Brief, p. 14). As the Commissioner pointed out (Ad., p. 11, 1st column), the record indicates otherwise (Tr. 32815-32822). Dr. Harper's concern for accuracy, and his correction of Senator Proxmire's inaccuracies, are simply not evidence of bias.

Not only did Dr. Harper refute Dr. Robinson's false assumptions, he affirmatively testified that he did not know of any occasion when anyone on the Board had been influenced by any member of the food industry in the setting of RDA's. He further explained that there were policies adopted by the Committee to assure that its members were not influenced by the food industry (Tr. 32589, 33381-33385). Nothing in the record suggests anything to the contrary.

2. The Board Appropriately Set The
RDA's At Levels To Provide
"Adequate" Health.

Dr. Robinson made it clear in his cross examination of Dr. Harper that he thought that the RDA's should be set at a level to provide "optimum health" to most people. He argues that the RDA's are inadequate because they are too low to provide such "optimum health" (Brief, pp. 18-20). The record indicates that the Board had good reason for setting RDA's to achieve "adequate health."^{6/}

On cross-examination, Dr. Harper explained that "optimum health" is an unscientific term that cannot be defined (Tr. 32573, 32582-32583). Dr. Harper further testified that the RDA's are set at a level that should "be adequate for most, hopefully all, healthy people in the United States" and that, since there is "no evidence that increased amounts that are recommended do anything to improve health," it would be "completely unscientific to propose larger quantities of nutrients for anyone on the basis of sheer rank speculation" (Tr. 32572-32573). Thus, it was not inappropriate for the Board to set the RDA's at levels to provide "adequate" health, or for the Commissioner to use the RDA's in setting the U.S. RDA's.

^{6/} Citations to pertinent portions of the transcript of the Reopened Hearing are found in the Addendum, p. 11, 2d column.

3. The Record Does Not Support The Allegation That The RDA's Were Established At An Unscientifically Low Level In Order To Fit The Current Food Supply.

Dr. Robinson has contended that the Board deliberately set the RDA's at levels that did not exceed the quantity available in the food supply (Brief, pp. 21-26). The Commissioner found this contention to be without merit.^{7/}

Dr. Harper testified that the amount of a nutrient in the food supply is only considered where two other sources of scientific information are not sufficient. The average individual requirement of a given nutrient is usually based on available information from experiments on human subjects in which objective criteria indicative of the sufficiency of nutrient intake or the lack thereof (e.g., night blindness) are employed and the amount of the nutrient required to meet those objective criteria has been met during the course of the experiment (Tr. 32969). If such data are not available, a second source of information is considered, namely the development of nutritional deficiency in a given population coupled with observation of the amounts of nutrients required to prevent, cure, or alleviate the signs or deficiency (Tr. 32969).

Only when both of these preferred sources of information are insufficient is the quantity of a nutrient provided in the food supply consumed by a particular population group considered (Tr. 32970). Further, the nutrient requirement figure derived from all considerations is not used as a ceiling for the RDA (Tr. 32969). Individual variabilities are taken into account. The nutrient requirement figure is adjusted upward, depending on a number of factors, including the use of sound statistical analysis, to establish allowances that are ample to meet the needs of the population of the United States (Tr. 32606, 32672-32674, 32801, 32970-32971, 32981, 33071, 33078).

^{7/} Citations to pertinent portions of the Transcript of the Reopened Hearing are found in the Addendum, p. 11, 2d column.

The procedures followed by the Committee and the Board in establishing the RDA's were explained at length by Dr. Harper (Tr. 33314-33317). Data concerning the amount of a nutrient provided by the food supply are only one of several types of information used by the Committee, and this method is scientifically sound.

Again Dr. Robinson misconstrues the record in his attempt to show that the Committee relied improperly on the food supply in establishing certain RDA's. For example, he states that "the Board frankly admits that its vitamin E 'allowances are based primarily on the d-alpha-tocopherol contents of diets'" (Brief, p. 21, citing the eighth edition of "Recommended Dietary Allowances" (1974)). However, as the Commissioner pointed out, this quotation was taken out of context. The quotation comes from a discussion about the manner in which food is analyzed to determine vitamin E content. Although there are various tocopherol compounds, because of insufficient analytical data, no tocopheral compounds other than d-alpha-tocopherol can be considered in dietary calculations (Ad., p. 11, 3d column). The relative contribution of other less active tocopherol compounds to the total vitamin E activity of diets in the United States has yet to be assessed. Therefore the discussion concludes that "until more values are available for the amounts of less active tocopherols and tocotrienols in foods and until the equivalency of these compounds to d-alpha-tocopherol is better established, allowances are based merely on d-alpha-tocopherol content of diets" (Id., p. 57). Thus, when this quotation is read in context, it is clear, contrary to Dr. Robinson's allegation, that the vitamin E content in food was not the sole basis for establishing the RDA for vitamin E. The NAS/NRC publication states that the recommended allowance for vitamin E is based "partly on available experimental evidence in man ... and partly on an estimate of the amount of vitamin E considered to be available in the United States food supply ..." (Id. p. 59).

Dr. Robinson also points out that the RDA for vitamin E was lowered in the 1974 "Recommended Dietary Allowances" and asserts (Brief, p. 21) that this was due solely to the Committee's reliance on the vitamin E content in the food

supply. However, as the record shows (Tr. 33359), this correction in the RDA for vitamin E was based upon a human study done by Dr. M. K. Horwitt that showed that it was only after four years of an intake of one seventh of the 1968 RDA that any sign of vitamin E deficiency could be detected in red blood cells (Tr. 33359).

Dr. Robinson further contends, "Dr. Harper agreed there were new sensitive criteria for detecting vitamin E deficiency which the Board did not use" (Brief, p. 21). But Dr. Harper stated there were papers referred to by the Committee which involved the more sensitive hemolysis test (Tr. 32397). Although there were more sensitive criteria than were used by Dr. Horwitt in the study previously mentioned, nothing in the record suggests that sensitive criteria were improperly ignored by the Committee in their deliberations or that these criteria would have made a significant difference in establishing the 1974 vitamin E RDA.

Dr. Robinson's next alleged example of the Board's improper reliance on the levels of nutrients available in the food supply for setting RDA's concerns vitamins E, C, B12 and thiamine for infants. He contends that the RDA's for these nutrients are all largely based on what is found in human milk. This contention, too, ignores portions of the record. The Commissioner noted, first, that for vitamin E and thiamine the allowances are also based in part on human studies (Tr. 33352 and "Recommended Dietary Allowances" (1974), pp. 59, 60, 67) (Ad., p. 12, 1st column). Second, Dr. Harper was cross-examined extensively on the infant level for vitamin E, the vitamin with which he is most familiar, and his testimony demonstrated that the scientific methodology was sound (Tr. 33350-33359). A study conducted by Dr. L. J. Filer, former Chairman of the Food and Nutrition Board, concerning the growth rates of infants fed human milk formula supported the RDA level for vitamin E (Tr. 33354).

Dr. Robinson considers it "a remarkable coincidence" that a government article entitled, "Nutrition in the United States: 1900-1974," by Willis A. Gortner of the U.S. Department of Agriculture, provides information about certain nutrients in the food supply that shows that the percapita supply of these nutrients in the food supply is "quite close" to the RDA's (Brief, p. 25). From this Dr. Robinson posits that "it may be safely assumed that the Board, with its close ties to the food industry, has been well aware of government food data reaching back to the year, 1900" (Brief, p. 25). Even if true, such would not "show" that the Board deliberately and unscientifically set the RDA's at a low level to coincide with the nutrients available in the food supply. The Commissioner rightly found this article to be of questionable relevance (Ad., p. 30, 2d column).

The Commissioner properly concluded that, to the extent that the Committee relied on the food supply to establish RDA's, it had done so in accordance with sound scientific principles (Ad., p. 12, 2d column and p. 30, 2d column).

4. The Record Supports The Statistical Methodology Used By The Board In Setting The RDA's.

Dr. Robinson attacks the statistical method used by the Board to determine the RDA's as being based on assumptions that are "scarcely documented and highly questionable" (Brief, pp. 26-39). Again the Commissioner reviewed the record and concluded that the statistical methodology used by the Committee in establishing the RDA's was scientifically sound.^{8/}

The Committee's allegedly "scarcely documented and highly questionable" assumption was the use of a 15 percent coefficient of variation. However, as the Commissioner noted, the record shows that the 15 percent figure was not arbitrarily assumed, but was based on a wide variety of biological measurements

^{8/} Citations to pertinent portions of the Transcript of the Reopened Hearing are found in the Addendum, p. 13, 1st column.

and individual studies in which the coefficient of variation came out to be 15 percent (Tr. 32612-32613, 32672-32674). Other appropriate references were relied on in arriving on this figure (Tr. 33132-33135). Dr. Harper testified he thought 15 percent was a reasonable figure, and that if there had been sound evidence for employing a different coefficient of variation for any nutrient, such a figure would have been employed (Tr. 32789). Dr. Harper testified that the coefficient of variation for vitamin C was changed from 38 percent in calculating the 1968 RDA's to 15 percent in the 1974 RDA's because more recent experiments had provided more reliable information so that a 15 percent coefficient of variation was appropriate (Tr. 33136).

Dr. Harper testified that the Committee used a Gaussian curve of normal (bell-shaped) distribution in establishing the RDA's. Dr. Robinson disagrees, and points out that Dr. Harper testified that there are biological phenomena for which the Gaussian distribution does not fit very well and alleges that if the distribution for a particular nutrient were non-Gaussian, the range of people not covered would be wide (Brief, p. 30). But Dr. Robinson does not acknowledge the fact that Dr. Harper never testified that such a non-Gaussian distribution was applicable to RDA's.

Yet the record shows that Dr. Harper testified: (1) the available information tends to show a Gaussian distribution (Tr. 33045), (2) there was no evidence that anybody's needs are higher than the RDA's developed using the Gaussian distribution (Tr. 33030), (3) the Gaussian distribution was not the only criterion used (Tr. 33051), (4) there are references that support the use of the Gaussian distribution (Tr. 33038-33039), and (5) the hypothesis has been successfully tested (Tr. 33045-33046).

In spite of this, the cross-examination of Dr. Harper conducted by Dr. Robinson's associate, Dr. Ronald R. Davis,^{9/} repeatedly involved hypothetical

^{9/} Dr. Davis is not an attorney.

questions which assumed a non-Gaussian distribution, totally ignoring Dr. Harper's testimony. For this reason the ALJ terminated this line of questioning. While it may be true that, if the curve is non-Gaussian, the RDA's might be low, Dr. Davis failed to establish there was any reason to believe that the curve was non-Gaussian.

Dr. Robinson contends, thirdly, that the Committee's statistical methodology was defective in that it treated each nutrient independently of the others rather than considering the simultaneous use of all nutrients. He states that Dr. Harper "confirmed" the Board did not consider the "statistical problem" involved in meeting the needs for more than one nutrient in a person (Brief, p. 31).

This is a mischaracterization of the record. Dr. Harper never agreed that this "statistical problem" was anything more than an unlikely hypothetical (Tr. 33082, 33109-33111, 33117). Dr. Harper testified that even if all nutrients were considered simultaneously, it was quite possible that the percentage of the population whose nutrient needs are met would not change. He further testified that the RDA's were set to exceed people's needs and that "you may well expect half the population to eat less than the RDA and still have their needs met completely" (Tr. 33078).

In this connection Dr. Robinson alleges, "the full extent and significance of the Board's statistical incompetence" could not be brought out at the re-hearing because the ALJ "improperly restricted crucial lines of inquiry in the cross-examination" (Brief, p. 38). It is true that the ALJ sustained an objection to the line of questioning Dr. Davis was pursuing concerning the Gaussian distribution. As demonstrated in the record, the reason the ALJ sustained the objection was that this line of questioning was highly repetitive. Dr. Davis had already cross-examined Dr. Harper extensively on this point (Tr. 33029-33051). The ALJ explained the reason for his ruling, and Dr. Davis indicated that he agreed (Tr. 33055).

The ALJ also ruled that certain hypothetical questions on statistical probability posed by Dr. Davis were irrelevant (Tr. 33076), because no foundation had been laid showing how these statistical hypotheticals related to the establishment of the RDA's (Tr. 33073-33074). Nevertheless, the ALJ allowed Dr. Davis to continue to pursue his point with a different hypothetical (Tr. 33076-33080).

The Commissioner properly determined there was adequate evidence in the record that the Board used proper statistical methodology in setting the RDA's and that the ALJ gave Dr. Davis great leeway and was exceedingly fair during his entire cross-examination (Ad., p. 13, 3d column).

5. The Record Supports The Limited
Use Of Animal Data By The Board
In Setting RDA's.

Dr. Robinson alleges that the Committee depended extensively on animal data, but at the same time rejected "crucial animal data" (Brief, pp. 39-54). He contends that "the Board pays attention to animal data only where this does not conflict with its bias aimed at holding the RDA's down to a level which will not embarrass the reputation of modern processed food, nor exceed the per capita ceiling of nutrients available with that food" (Brief, p. 48). After examining the record, the Commissioner concluded that it did not support these contentions.^{10/}

The Commissioner noted that the eighth edition of "Recommended Dietary Allowances" (1974) does mention some animal studies, and that it appears that animal studies were used to determine the relative effectiveness of various forms of some vitamins (Tr. 32873, 32875) and the availability of some vitamins in food (Tr. 32874). However, it does not appear that such studies were extensively relied upon.

^{10/} Citations to pertinent portions of the transcript of the Reopened Hearing are found in the Addendum, p. 12, 2d column.

Dr. Harper testified on the manner in which the Board used animal data. He stated that the Board does not depend extensively on animal data and then extrapolate to human values; that it is only after human values are obtained that data derived from animal studies are occasionally used to make comparisons (Tr. 32852-32853, 32883). Further, Dr. Harper testified that even if there is a discrepancy between the animal value and the human value, this would not necessarily invalidate the human value (Tr. 32853). Dr. Harper also testified that no animal studies are directly used in estimating the human requirements of vitamins A, D, E, C, folic acid, thiamine, riboflavin, niacin, vitamin B12, phosphorous, iron, magnesium, zinc, iodine, and vitamin B6 (Tr. 32872-32875).

By cross-examination Dr. Robinson attempted to show that the Committee rejected "crucial" animal data that allegedly indicated that the nutrient requirements for certain animals were higher than those recommended for man in the RDA's by citing a National Academy of Sciences publication entitled "Number 10 - Nutrient Requirements in Laboratory Animals" ("Number 10"). When asked whether he had relied upon this publication in establishing the RDA's, Dr. Harper testified that he had not (Tr. 32879). Dr. Harper explained that when the Board made comparisons between human and animal studies, it would rely upon materials containing original experimental data. The NAS publication was simply a guide for use in feeding animals for laboratory experimentation, and it contained only a summary of experimental data available in scientific literature. It was therefore inadequate to use for comparison (Tr. 32879). Also, Dr. Harper testified that frequently the figures used in this publication are based upon types of diets that have maintained normal growth in animals and that there is often no effort to determine specific requirements (Tr. 32894). Finally Dr. Harper testified that he did not know of any good summaries of comparative animal requirements (Tr. 32894).

For this reason the ALJ did not admit into evidence Dr. Robinson's bar graphs comparing the Board's RDA's with the RDA's for feeding laboratory animals during experimentation appearing in the NAS publication "Number 10." Such a decision was certainly not error. Nevertheless Dr. Robinson cross-examined Dr. Harper extensively on the possible implications of the data contained in this exhibit.

Finally, Dr. Robinson alleges that "the real reason why the Board did not present nutrient requirements (in a per kilocalorie of food basis) was that it would dispel much of the obfuscation by which the Board maintains its elite, and also lead to an embarrassing comparison with the more precisely determined animal requirements" in "Number 10" (Brief, p. 50). To support this contention Dr. Robinson refers to Dr. Harper's admission that the Board had considered using this form for expressing allowances in the 1974 report on RDA's. Dr. Robinson discounts Dr. Harper's explanation that the Board's reason for not doing so was its decision that "a table (using per kilocalories) was not a very effective way of reporting the values" (Tr. 32892), but he points to no evidence in the record to support his theory.

6. There Is Sufficient Evidence In The Record To Support
The Levels Set For Vitamins A, D, E, And C.

In his cross-examination of Dr. Harper, Dr. Robinson probed the basis on which the Board set certain RDA's. He now alleges that the Committee ignored certain criteria in setting RDA's for vitamins A, D, E, and C (Brief, pp. 54-59). In each case the Commissioner found that the Board had an adequate scientific basis on which to set the challenged RDA, and in each case the Board had good reason for not utilizing the criteria suggested by Dr. Robinson (Ad., p. 14, columns 1 and 2).

For example, the criterion for adequate nutrition for vitamin A used by the Board was the absence of night blindness. Dr. Robinson alleges that the

Committee should have considered the vitamin A content of the liver and the fact that a larger daily allowance of vitamin A was recommended in "Number 10" for laboratory animals (Brief, p. 55). Dr. Harper testified that to the best of his knowledge, no one had ever performed liver biopsies on human subjects during the development of vitamin A deficiency and that, while he wasn't certain, he thought it was highly probably that night blindness would be one of the first discernible symptoms of vitamin A deficiency (Tr. 33426-33427).

Moreover, when the Committee and Board established the RDA for vitamin A, they were fully aware that the liver was the center for the storage of that vitamin and that ingestion of excessive amounts of vitamin A results in very large accumulations of vitamin A in the liver, which can cause toxicity (Tr. 33430). Therefore the relationship between vitamin A and the liver was considered in establishing this RDA even though this criterion was not utilized because it would not have been practicable to do so.

At the hearing Dr. Harper acknowledged that the rat needs 19 times more vitamin A than normal during pregnancy while the human needs only 3 times more. He explained that the rat produces a litter of 12 and can produce a litter every 21 days, so that the proportion of the rat's body weight that may be involved in maximum reproduction is about 1/5 every 28 to 38 days, whereas a woman would use 1/8 to 1/9 of her body weight every nine months (Tr. 33437-33438). This fact accounts for the difference in animal and human need for vitamin A during pregnancy and further explains the inappropriateness of basing human RDA's on animal RDA levels.

Dr. Robinson says he "has no quarrel" with the level of RDA set for vitamin D, but he questions the fact that the Committee made no distinction between the two common forms of vitamin D-1(D-2 and D-3) and alleges that the synthetic form, D-2, is less effective than the natural form found in animal products, D-3 (Brief, p. 56). He points out that "Number 10" states that some monkeys suffer demineralization of the bone on the artificial D-2.

Dr. Robinson admits that Dr. Harper testified that the question of the relative effectiveness of the two forms of vitamin D was discussed with the Committee member on the Board responsible for determining an RDA for this vitamin (and other experts), and that Dr. Harper testified that they found no evidence to suggest that one form of the vitamin should be designated as the exclusive source of vitamin D for human supplementation (Tr. 33472).

Dr. Harper also explained that the study Dr. Robinson referred to did not involve vitamin D deficiency but rather the utilization of vitamin D-2 to attempt to cure a bone disease (Tr. 33467). Furthermore, Dr. Harper testified that the study indicated that the Rhesus monkey, which is the one most widely used in nutritional studies, responds equally well to both forms of vitamin D-1, and it was only some species of the South American monkey that showed a difference (Tr. 33467-33468).

Dr. Robinson attempted to explore the reasons for the Board's lowering the RDA for vitamin C in 1974. However, the Administrative Law Judge did not allow this line of questioning because the U.S. RDA's were based on the 1968 RDA's, not the 1974 RDA's. Since the remand instructions of the Court were to permit cross-examination as to the basis of the RDA's on which the regulations were based (512 F.2d at pp. 792-799), the Commissioner determined that the Administrative Law Judge properly excluded all questioning concerning the difference between the 1968 and the 1974 RDA levels (Ad., p. 14, 2d column).

7. There Was No Error In The Administrative
Law Judge's Procedural Rulings.

Dr. Robinson claims that the ALJ erred by making inequitable and improper procedural rulings. He even accuses the ALJ of "unfairly harassing" him (Brief, pp. 60-65). The Commissioner properly rejected these allegations as being without merit.^{11/}

^{11/} Citations to pertinent portions of the transcript of the Reopened Hearing are found in the Addendum, p. 14, 2d and 3d columns.

The record indicates that the ALJ was fair to all participants, including Dr. Robinson. At the prehearing conference, the ALJ stated that he would hold attorneys to a higher standard than non-attorneys (Pretrial Hearing Tr. p. 12). This was to Dr. Robinson's benefit because he is not an attorney. Following this promise throughout the proceedings, the ALJ was extremely fair to Dr. Robinson in giving him leeway to ask questions which either bordered on being or were in fact objectionable. The ALJ also explained his rulings whenever Dr. Robinson became confused. He even gave guidance to Dr. Robinson because he was generally unfamiliar with the rules of evidence and proper cross-examination.

The Commissioner noted examples of the ALJ's fairness (Ad., p. 14, 3d column). Dr. Robinson asked and received advice on the proper technique for making a motion (Tr. 32499); the ALJ encouraged Dr. Robinson not to give up so quickly on the line of questioning to which an objection has been raised (Tr. 32501); the ALJ patiently explained the proper way to use exhibits (Tr. 32508-32509); the ALJ allowed Dr. Robinson a recess when he became confused and asked for time to consult with a lawyer (Tr. 32580-32581); and the ALJ allowed Dr. Robinson to introduce an exhibit without first providing copies to other parties and counsel to FDA as required by the rules (Tr. 32599).

Finally, even Dr. Robinson commented on the ALJ's fairness during the hearing. In introducing Dr. Davis, who had no prior experience in cross-examination but was about to cross-examine Dr. Harper, Dr. Robinson said, "I'm confident that under Your Honor's impartiality and fair guidance that all will be well" (Tr. 33029). Subsequently, Dr. Robinson again commented on how fairly Judge Davidson had conducted the hearing, noting "I feel that you are absolutely fair if you insist that the cross-examination be relevant and material and not repetitive. Personally, I am very satisfied that we are getting down to what Judge Friendly wanted ***" (Tr. 33362).

In this context the ALJ was aware of the history of this litigation and this Court's expressions on the prior proceedings. With this in mind and based on an examination of the entire record of the reopened hearing, it can only be concluded that the ALJ afforded Dr. Robinson and the other parties a fair hearing.

This does not mean that Dr. Robinson and the ALJ always agreed. In the hearing Dr. Robinson, while not an attorney, was certainly an advocate who demonstrated with zeal and devotion a strong belief in his arguments and position. As is true in the courtroom, an administrative hearing that goes on for six days will almost always have some moments when the advocate and the ALJ do not agree. Nothing of this sort warrants reversal because of prejudice when in fact there was none. Thus, if at times the ALJ became impatient with Dr. Robinson, an examination of the record usually discloses some provocation (e.g., the portion of the record quoted by Dr. Robinson on p. 62 of his brief, Tr. 33521-22). But impatience does not show bias, much less the substantial showing of bias required to justify a ruling that a hearing was unfair. Roberts v. Morton, 549 F.2d 158 (10th Cir. 1976); Converse v. Udall, 262 F. Supp. 583 (D. Or. 1966), aff'd, 399 F.2d 616 (9th Cir. 1968), cert. denied, 393 U.S. 1025 (1969).

The ALJ's decisions regarding the starting hour and duration of each day's hearing, the attendance requirements for those parties who desired to cross-examine the witness, the availability of a "next day transcript," and the admissibility of evidence, all fell within the ALJ's wide latitude of authority and discretion with respect to all phases of the conduct of the hearing, including the manner in which the hearing proceeds. Fairbank v. Hardin, 429 F.2d 264 (9th Cir. 1970), cert. denied, 400 U.S. 943 (1970); Cella v. U.S., 208 F.2d 783 (7th Cir. 1953), cert. denied, 347 U.S. 1016 (1954). The fact that the ALJ ruled against Dr. Robinson on these matters certainly does not show bias. Converse v. Udall, supra. In N.L.R.B. v. Acme-Evans Co., the Seventh Circuit said, "The heat of the

contest has, we think, led respondent to attribute bias because of its own feelings." ^{12/}
130 F.2d 477, 482 (1942). These words seem appropriate here.

Nor was the ALJ's refusal to permit Dr. Robinson to introduce rebuttal testimony reversible error. From the beginning of the hearing process, the ALJ made it clear that, pursuant to the remand directions of the Court of Appeals, the reopened hearing was for the limited purpose of cross-examination of one qualified member of the Board, and that rebuttal would not be allowed unless exculpation for impeachment of the witness were shown (Pre-trial Hearing Tr. 63-64).

At the close of the hearing Dr. Robinson stated that he wanted to introduce rebuttal testimony with respect to statistical methodology, use of animal data, and alleged defects for certain RDA's. The ALJ gave him opportunity to explain his reasons for seeking rebuttal (Tr. 33495-33500). The ALJ considered Dr. Robinson's reasons and concluded:

As I said many times before on the record, this is an unusual situation to have a proceeding remanded solely for the purpose of cross-examination. It carries with it some unusual problems for everyone, including myself. This is one of them.

As I said before at the Pre-Hearing conference, and I am sure on numerous occasions throughout the proceeding here, if the opponents could show some specific area of information that only came to light in the cross-examination which was relevant and material to the point that it required the need for rebuttal evidence, I would take that under advisement, and I would rule on it at the conclusion of the cross-examination.

I have heard Dr. Robinson's argument, and there are certain things that he says which do raise slight questions, but I am satisfied that they don't raise sufficient problem for me to be concerned with granting a request for rebuttal evidence. As I view the proceedings, as I said before, the evidence was before the parties. The opposition had its opportunity to present rebuttal. True there were certain

^{12/} Dr. Robinson's spurious claim that the ALJ engaged in ex parte communication and violated separation of functions is answered by the Commissioner in the Addendum, p. 15, 1st column.

aspects of how the Food and Nutrition Board operated which were not brought to light until we had cross-examination; nevertheless, the RDA's were available. The seventh edition was available. Any scientific evidence that was available to the opponents could have been introduced into the evidence on this record to show the resulting RDA's were improper or the wrong level or should have been at a different level, and that opportunity, as far as I'm concerned was sufficient to have met the need for rebuttal. (Tr. 33502-33503).

The Commissioner concluded (Ad., p. 15, 2d column) that the extensive cross-examination of Dr. Harper was sufficient for the purpose of the remand, especially since, as a result of the 1976 Vitamin and Mineral Amendments, the U.S. RDA's are no longer used to restrict the maximum potency of vitamins and minerals in most dietary supplements for adults. Indeed, the Commissioner understood this Court to have held that the remand would not have been necessary if the U.S. RDA's had not been used to limit potency (Ad., p. 10, 2d column, citing 504 F.2d at 799). Thus, he correctly concluded that no rebuttal was needed nor was it required by the decision of the Court of Appeals.

Finally, the government thinks Dr. Robinson's difficulty with this case is not so much in some procedural decisions of the ALJ or in certain conclusions of the Commissioner, but rather in the law applicable to rulemaking on a record under Section 701(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(e)) and appropriate provisions of the Administrative Procedure Act (5 U.S.C. 553 et seq.). Dr. Robinson believes sincerely that the RDA's on which FDA's U.S. RDA's are based are wrong. They are too low to assure "optimum health." He believes he knows the reason for the low RDA's, a conspiracy by the food industry that includes Dr. Harper and the Board. What Dr. Robinson cannot understand is that sincere belief, however passionately held, is simply not adequate to overcome "substantial evidence of record" presented in an administrative hearing.

Yet that is what has happened in this case. This Court has previously sustained the use of the RDA's in setting the U.S. RDA's, subject to Dr. Robinson's cross-examination of a qualified member of the Board and the admitted unlikelihood that vigorous cross-examination would shatter the bias underlying the 1968 RDA's (504 F.2d at 700, fn. 65)

That cross-examination has now taken place. The record shows that Dr. Robinson never demonstrated any bias by Dr. Harper or the Board, and that substantial evidence was presented to enable reasonable minds to accept the ALJ's and Commissioner's conclusions that the Board had a rational basis for using a standard of adequate health rather than optimum health in setting the RDA's; that scientifically sound procedures were followed in the use of animal data and statistical methodology; and that the RDA's were amply supported, however imperfect the state of current nutritional knowledge may be. School Board of Broward City, Fla. v. HEW, 525 F.2d 900 (5th Cir. 1976); Rivas v. Weinberger, 475 F.2d 255 (5th Cir. 1973). The Commissioner's decision should be sustained.

II. The FDA Has Lawfully Promulgated
Final Revised Regulations Governing
The Labeling And Composition Of
Dietary Supplements Of Vitamins And
Minerals.

Petitioners NNFA pose a series of challenges to the final revised regulations at issue in this case the effect of which, if successful, would be to set aside all that has transpired to date and begin de novo the process of designing and promulgating a regulatory scheme to govern dietary supplements. The recurring theme in their challenges is that the passage of the 1976 Vitamin and Mineral Amendments (the Amendments) so alters the regulations promulgated in 1973 and broadly sustained by this Court that the entire regulatory scheme needs to be reconsidered, presumably with a new proposal and another adjudicatory hearing.

Admittedly, the Amendments cut into the heart of the Agency's regulatory scheme for dietary supplements by restricting the FDA's authority to limit the inclusion of ingredients and maximum potency of vitamins and minerals in dietary supplements which are offered for use by adults, other than pregnant or lactating women, and are recognized as safe. But the Agency has chosen to retain the original regulatory scheme as much as possible. Accordingly, on October 19, 1976 the FDA promulgated final revised regulations incorporating the specific changes ordered by this Court and the Congress (41 F.R. 46136-46176 (Ad., pp. 8-28)).

The remand instructions of the Court have been punctiliously followed. The regulations have been amended to conform to the Amendments. The final revised regulations are lawful and should be sustained. The question of whether to design a new scheme to regulate vitamin and mineral dietary supplements or utilize the original scheme to the fullest extent possible rests with the Agency.

Mourning v. Family Publications Service, Inc., 411 U.S. 356, 371-2 (1973); Graham v. National Transportation Safety Bd., 530 F.2d 317, 319 (8th Cir. 1976).

1. There Was No Need For The Agency
To Give Further Opportunity For
Comment On The Revised Regulations.

NNFA first argues that the regulations should be vacated because FDA failed to give proper notice and opportunity for comment prior to promulgating them as final rules (Brief, pp. 7-18).

In Public Law 94-278, Congress ordered that "The Secretary of Health, Education, and Welfare shall amend any regulation promulgated under the Federal Food, Drug, and Cosmetic Act which is inconsistent with" the Amendments (Pub. L. 94-278, Title V, April 22, 1976).

Congress further ordered "such amendment shall be promulgated in accordance with Section 553 of Title 5, United States Code." Normally regulations such as the ones at issue in this case that set standards of identity under Section 401 of the Act (21 U.S.C. 341) and prescribe labeling for foods for special dietary

to its structure. The Commission's responsibility for the maintenance of the United States is of the U.S.A. It is not that in this case the "single matter" which the Commission is required to deal with is of the U.S.A. but with a complex situation of which it is a part. It is not that the maintenance of the Commission has been established. United States v. United States, 107 F. 2d 1002 (D.C. 1941).

It seems apparent to the Commission that anybody would question the Agency's prompt compliance with a direct mandate of the Congress of the United States. But NFA did. It submitted a "request" petition requesting the withdrawal of the regulations as final orders and the granting of an opportunity for the submission of comments. In the Federal Register of April 13, 1977 Vol. 42, pp. 27-33, the Agency denied NFA's petition and, having to belabor the decision, explained in detail how the Agency's rule notice and further public procedure impracticable, unnecessary, and contrary to public interest. This was hardly, as NFA suggests, a "post hoc explanation" (Brief, p. 9); it was an elaboration of the finding and explanation of reasons that had been given in the October 19, 1976 notice.

Now NFA asks this Court to reverse the Agency's decision and require notice and comment procedures. Petitioners' brief goes into a lengthy discussion of case law and legislative history interpreting the meaning of "impracticable," "unnecessary," and "contrary to the public interest." Respondents acknowledge that this precise situation has not been before the Courts and was not addressed in the House and Senate Reports. But then this situation is unique: a federal agency, operating under its existing statutory authority, promulgated regulations using procedures that included an adjudicatory hearing. After the regulations were broadly sustained by the Court of Appeals, certain parties, including petitioners, went to the Congress and persuaded the Congress to pass legislation which, when implemented by the agency (as the agency was required to do by the legislation), had the effect of excising certain provisions of the agency's previously promulgated and broadly sustained regulations.

This is the kind of situation which, on its face, qualifies for the exemption of Section 553(b) (B) of the A.P.A. The Congress has spoken, in public; the agency must comply. Further public procedures are unnecessary. "The role of the agencies remains basically to execute legislative policy; they are no more authorized than are the courts to rewrite acts of Congress." Talley v. Mathews, 550 F.2d 911, 919 (4th Cir. 1977). Nor, for that matter, is the public. The Amendments specifically affected certain provisions of the dietary supplement regulations pertaining to the limitation of ingredients offered and maximum potency. There was nothing left for the public, or the Agency, to say about the policy. When the words of a statute are clear, there is no need to go behind them into the legislative intent, Ernst & Ernst v. Hochfelder, 96 S.Ct. 1375 (1976); Holtzman v. Schlesinger, 484 F.2d 1307 (2d Cir. 1973), cert. denied, 416 U.S. 936 (1973). This is especially true when the result is not inconsistent with the purpose of the statute. Fortnightly Corp. v. United Artists Television, 392 U.S. 393 (1968). Section 553(b) (B) is clear: if notice and public procedure are impracticable, unnecessary, or contrary to public interest, they may be omitted. That is what the Commissioner did in promulgating these final revised regulations. His action is lawful.

NNFA contends that the need for further comment is demonstrated by the fact that certain provisions of the revised final regulations are contrary to the spirit and intent of the Amendments, and that if there had been opportunity for comment, these provisions would have been amended. Points II - VII in the NNFA brief treat these alleged errors. As will be shown in Points 2 - 7 below, the challenged provisions are consistent with the law.

2. The Standard Of Identity For Dietary Supplements Intended For Use By Pregnant Or Lactating Women And Children Is Lawful.

NNFA contends that FDA improperly promulgated the standard of identity for dietary supplements intended for use by pregnant or lactating women and children under the age of twelve years (Brief, pp. 18-21).

The Amendments that restrict FDA's authority to limit the inclusion of ingredients and maximum potency of vitamins and minerals in dietary supplements specifically provide that this restriction

shall not apply in the case of a vitamin, mineral, other ingredient of food, or food, which is represented for use by individuals in the treatment or management of specific diseases or disorders, by children, or by pregnant or lactating women. For purposes of this subparagraph, the term 'children' means individuals who are under the age of twelve years (21 U.S.C. 411(a)(2)).

The Conference Report explained the reasons for this exception:

The conferees are also concerned that attention should be given to those vitamin and mineral preparations that are not intended for use by infants, children or pregnant or lactating women, but may be taken by or administered to them inadvertently. Just as the fetus may be affected by excessive doses of some food supplements, excessive doses of vitamins and minerals by children during the period of rapid growth and maturation can interfere with their normal development. Because of such possibilities of unrecognized or unanticipated harm, it is intended that the Secretary retain full authority to promulgate regulations designed to assure that unsuitable or inappropriate vitamin and mineral preparations are not inadvertently administered to individuals in these vulnerable groups (H.R. Rep. No. 94-1005, 94th Cong., 2d Sess, 26 (1976)) (Conference Report)).

Therefore there is nothing illogical, as NNFA contends (Brief, p. 1C), in setting a standard of identity for vitamin and mineral dietary supplements for these particular groups.

Nor is there anything arbitrary about the Agency's "automatic continuation" of the previously proposed adopted and sustained (subject to consideration of further applications), potency and combination restrictions, since these restrictions are based on an "objective standard." The RDA's used by the Agency to establish the U.S. RDA's set separate levels for infants, children under four years of age, adults and children of four or more years of age, and pregnant or lactating women. The appropriateness of using the RDA's as a basis for the U.S. IJA's was discussed in documents in the Federal Register of January 19, 1973 (38 F.R. 2125-2132, 2143-2150, 2152-2162) and August 2, 1973 (38 F.R. 20708-20718, 20730-20740, 20745). This Court

has affirmed the FDA's authority to use RDA's to regulate the labeling and composition of dietary supplements (504 F.2d at 789-792), subject to the outcome of the reopened hearing. And the testimony of Dr. Harper at the reopened hearing reconfirmed the validity and usefulness of the RDA's as a basis for the U.S. RDA's. Thus it is simply not true to say, as NNFA does, that the standard of identity for these dietary supplements is "without any factual support or evidence in the record" (Brief, p. 21).^{14/}

3. The Agency Properly Retained
Minimum Potency Requirements
For Dietary Supplements.

Section 105.85(c) (§ 80.1(c), Ad., p. 23, 3d column) of the revised final regulations provides that dietary supplements shall contain in the specified daily quantity not less than the lower limit specified in § 105.85(d) (1) for the groups for which the supplement is offered (generally, 50 percent of the U.S. RDA). NNFA contends that FDA erred in retaining this minimum potency requirement (Brief, pp. 21-24). NNFA's argument is intriguing. The Amendments require FDA to permit the inclusion in dietary supplements of non-vitamin and non-mineral ingredients that the FDA considers to be totally worthless and have no known significance in human nutrition. Therefore, asks NNFA, how can the Agency justify the exclusion of what it considers insignificant amounts of vitamins and minerals when it must permit inclusion of other ingredients which it considers worthless? (Brief, p. 23) In other words, since FDA cannot protect the public as much as it wants to, it should not try to protect the public at all.

^{14/} One of the remand requirements of this Court was that the Agency invite applications for approval of additional formulations of dietary supplements. Three applications were submitted for a pediatric dietary supplement preparation containing vitamins A, D and C. One of these applications requested inclusion of vitamin E; another requested the optional inclusion of iron. In the Federal Register of October 19, 1976 (Ad., p. 9, 2d column), the Commissioner amended the regulations to include this supplement with optional inclusion of vitamin E and/or iron.

But that is a policy decision for the Commissioner. The law permits FDA to prescribe minimum potency requirements for dietary supplements under Sections 403(a) and 201(n) of the Act (21 U.S.C. 343(a) and 321(n)). In fact, the Conference Report specifically reaffirms the Agency's authority to do so:

This provision (the Amendments) would not restrict the Secretary (FDA) from proscribing minimum potency levels for vitamins and minerals in such products in order to prevent the addition of insignificant or useless amounts (At 26).

Further, this Court has held that there is nothing arbitrary or capricious in the Agency's drawing a line, in this case, at 50 percent of the U.S. RDA for the minimum potency requirements (504 F.2d at 792, fn. 43). This provision of the regulations is lawful.^{15/}

4. FDA Properly Continues Limitations
On The Maximum Quantities Of Components
Of Dietary Supplements.

Section 105.85(g) (2) (§ 80.1(g) (2), Ad., p. 25, 1st column) of the revised final regulations provides that:

Any safe and suitable substance may be used as preservative, stabilizer, flavor, sweetener, color, seasoning, carrier, base, or vehicle, or to facilitate preparation of vitamin or mineral substances. A dietary supplement shall be prepared so that any such substance contained therein does not exceed the amount reasonably required to accomplish its intended physical or technical effect, and so that the biological availability of the vitamin(s) and mineral(s) is not impaired by the presence of such substance.

NNFA contends that FDA erred in retaining these limitations on the maximum quantities of components of dietary supplements (Brief, pp. 24-26).

^{15/} NNFA claims that the regulations are inconsistent because 21 CFR 101.9(c) (7) (v) says that "No claim may be made that a food is a significant source of a nutrient unless that nutrient is present in the food at a level equal to or in excess of 10 percent of the U.S. RDA in a serving (portion)." There is no inconsistency. That provision pertains to claims that may be made on a label for the amount of a nutrient naturally occurring in a food which constitutes a portion of a meal. The regulation in the instant case pertains to a dietary supplement represented to provide a significant amount of a daily supply of a vitamin or mineral.

NNFA admits that this provision is carried over verbatim from the regulations as promulgated on August 2, 1973 (Brief, p. 25). NNFA also admits that this provision is based on the Agency's Finding of Fact Number 27 (38 F.R. 20736 (August 2, 1973)). NNFA fails to acknowledge that this provision is within the regulations which this Court has already sustained.

NNFA's objection is that "there is no basis for limiting a safe quantity of these substances when all other substances may be freely included in dietary supplements in any safe quantity" (Brief, p. 26). This is NNFA's recurring argument: if FDA is precluded from placing some limitations on dietary supplements, it should not place any limitations on them.

Significantly, NNFA omits the basis for the requirement in its quotation of the regulation and the Finding of Fact 27, namely, that "the biological availability of the nutrients in the dietary supplement should not be impaired by the presence of such substances." In other words, this provision is to assure the safety and effectiveness of the dietary supplement.

This is entirely consistent with other regulations. Section 172.5 of Title 21 of the Code of Federal Regulations contains the general provisions for direct food additives used as preservatives, coatings, films, and anticaking and flavoring agents, and requires that "the quantity of the substance added to food ... not exceed the amount reasonably required to accomplish its intended effect in food."

NNFA suggests that FDA might use this provision to limit the use of such substances as rutin and bioflavonoids (Brief, p. 26). But the Commissioner acknowledged in the Federal Register of April 19, 1977 (Ad., p. 31, 2d column) that these similar substances which have in the past been represented as having nutritional properties but which have not been shown to be essential to human nutrition may not be restricted as a result of the Amendments. It is foods that have been represented as having nutritional properties that the Congress sought to

protect from FDA restriction, not substances added for technical or functional effects.

5. The Nomenclature Required By The Regulations Is Lawful.

NNFA claims that the new legislation should prevent the Agency from "mechanical reliance" on the Court of Appeals' prior sanction of the reservation of the terms, "multivitamin" and "multimineral," to supplements containing the full spectrum of mandatory vitamins and/or minerals in appropriate amounts (Brief, pp. 26-29).^{16/}

The fact is that not only did this Court sustain the nomenclature restrictions of § 105.85(h) (§ 80.1(h), Ad., p. 25, 1st column) (504 F.2d at 785, fn. 29), but also the Congress specifically stated that "the Secretary retains the authority to initiate enforcement actions against a product to which the conference substitute is applicable if its labeling is false or misleading in any particular" (Conference Report at 29). The Commissioner announced in the Federal Register of April 19, 1977 that although Congress had now authorized multivitamin supplements containing less than the full spectrum of needed vitamins and/or minerals, it would not be proper to allow such preparations to be labeled as "multivitamin" or "multimineral" preparations because use of these particular terms would cause confusion with the full-spectrum "multivitamin" and/or "multimineral" preparations, in violation of 21 U.S.C. 343(g) and would also be misleading, in violation of 21 U.S.C. 343(a) (Ad., p. 32, 2d column).^{17/} Accordingly, this provision is lawful.^{18/}

^{16/} This reservation was not added for the first time and without prior notice and opportunity for comment in the April 19, 1977 Notice, as NNFA states (Brief, p. 27). This reservation was included in the October 19, 1976 final regulations (§ 80.1(h)(2) Ad., p. 25, 1st column) because the Commissioner concluded (Ad., p. 32, 2d column) that it was necessary as a matter of law to prevent consumer confusion.

^{17/} At the same time the Commissioner modified the label requirements for non-conforming preparations. The October 19, 1976 provision (§ 80.1(h)(2)(vii), Ad., p. 25, 2d column) required as part of the name "a term that is accurately descriptive of its vitamin or mineral composition." The April 19, 1977 notice requires "an appropriate descriptive term (Ad., p. 32, 1st column). This is a refinement without a difference

^{18/} There is no inconsistency, as NNFA claims (Brief, p. 28), between § 105.85(d) (80.1(d)) stating that folic acid is "mandatory" and, in § 105.85(b)(1) (80.1(b)(1)) stating that its use is optional in liquid dietary supplements "because of instability of the vitamin in liquid preparations".

6. The Vitamin And Mineral Amendments
Prohibit (a) "Dietary" Claims On
Labeling For Non Vitamin And Mineral
Food Ingredients And (b) Representations
That A Vitamin Or Mineral Is Effective
In The "Prevention" Of Disease.

Section 105.60(b) (125.2(b), Ad., p. 27, 3d column)) of the revised regulations provides as follows:

A food which purports or which is represented to be a food for special dietary use shall be deemed to be misbranded under sections 201(n) and 403(a) and (j) of the act if its labeling bears any statement, vignette, or other printed or graphic matter that represents, suggests, or implies:

(1) That the food, because of the presence or absence of certain vitamins and/or minerals, is adequate and effective in the prevention, cure, mitigation, or treatment of any disease or symptom, except that the label may state that the food is a source of an essential nutrient and that this nutrient is important for good nutrition and health, and except that the provision shall not apply to foods represented for use solely under medical supervision in the dietary management of specific diseases and disorders.

(5) That the food had dietary properties when such properties are of no significant value or need in human nutrition.

These provisions were considered by the Court of Appeals and sustained (504 F.2d at 801, 804-805). NNFA contends (Brief, pp. 29-34) that these provisions are inconsistent with the definition of the term, "food for special dietary use," in the Amendments and therefore improperly prohibit "dietary" claims for non vitamin and mineral food ingredients and representations that a vitamin or mineral is effective in the "prevention" of disease. As a matter of fact, these challenged provisions codify in the regulations specific provisions of the Amendments.

(A) "Dietary" Claims. Section 411(b)(2)(A) of the Act (21 U.S.C. 350(b)(2)(A)), being a portion of the Amendments, states that ingredients that are not vitamins or minerals may not be listed on the labeling of a preparation to which the legislation applies except as part of a list of all ingredients in the product.

The effect of this provision is to preclude the listing of any ingredients that are ^{19/} not vitamins or minerals on the "principal display panel" or "information panel."

Such non vitamin or mineral ingredients may only be listed in the separate ingredient list which includes all ingredients used in the manufacture of the product including preservatives, stabilizers, flavors, sweeteners, colors, carriers, bases, etc., in descending order or predominance by weight. However, the Amendments permit the advertising of the product to feature those nonnutritional ingredients provided that the labeling and advertising do "not give prominence or ... emphasize" ingredients which are not vitamins, minerals, or representd as a source of vitamins or minerals (21 U.S.C. 350 (b) (2) (B)).

The reason for this provision is explained in the Conference Report at follows:

Under the conference substitute, the Secretary retains the authority to initiate enforcement actions against a product to which the conference substitute is applicable if its labeling is false or misleading in any particular. In addition, the conference substitute contains special provisions respecting the labeling and advertising of these products.

The conference substitute provides that a food to which the conference substitute is applicable shall not be deemed misbranded under Section 403 of the Act solely because its label bears a listing of all of the ingredients in the food, or solely because its advertising contains references to ingredients in the food that are not vitamins or minerals. Thus, for example, if a tablet or capsule of vitamin C contains rutin, a substance that the Secretary has concluded has no dietary usefulness, the list of ingredients as we'll as the advertising for the product may refer to rutin without causing the food to be deemed misbranded. However, because of the conferees' concern that consumers not be misled into a belief that

^{19/} The term "principal display panel" ... means the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale (21 CFR 101.1).

The term "information panel" ... means that part of a label immediately contiguous and to the right of the principal display panel ... (21 CFR 101.2).

such substances have nutritional value, the conference substitute provides that the labeling so (sic) such a product may not list ingredients that are not vitamins or minerals except as a part of all the ingredients of the food, in accordance with the applicable regulations promulgated by the Secretary pursuant to Section 403 of the Act. ... Further the conference substitute provides that the labeling or advertising of a food to which the conference substitute is applicable may not give prominence to or emphasize ingredients which are not vitamins or minerals or are not represented as a source of vitamins or minerals (At 29).

NNFA goes through a torturous argument (Brief, pp. 30-31) to try to show that there is some inconsistency between the definition of "foods for special dietary use" and the prohibition of representing that a non vitamin or mineral ingredient has "dietary" properties. But there is no inconsistency in the Congress' saying that "food for special dietary use" may contain vitamins, minerals, and/or "other ingredients" but may not represent that those "other ingredients" have dietary properties "when such properties are of no significant value or need in human nutrition."

(B) "Prevention" of Disease Claims. NNFA claims that the Agency erred in continuing to prohibit labeling claims that a dietary supplement "prevents" disease.

The Amendments codified in Section 411 of the Act apply to food for humans, not to drugs. The Conference Report states,

If a product containing vitamins, minerals or other ingredients is a drug within the meaning of Section 201(g) of the Act, the Secretary may, with respect to such product, exercise his authority under Chapter V of the Act. For example, the Secretary may bring an action for misbranding of a product which purports to be or is represented as a drug (within the meaning of Section 201(g) of the Act) if its labeling fails to bear adequate directions for its purported use or for the use for which it is represented (within the meaning of section 502(f) (1) of the Act) (At p. 28).

Section 201(g) (1) (B) of the Act (21 U.S.C. 321(g) (1) (B)) defines the term "drug" as "articles intended for use in the diagnosis, cure, mitigation, treatment,

or prevention of disease in man or other animals...." If the label represents that a product is effective in the "prevention" of a disease, it is a drug. National Nutritional Foods Association v. Mathews, 557 F.2d 325 (1977); Rutherford v. U.S., 542 F.2d 1137 (10th Cir. 1976); U.S. v. Article ... Consisting of 216 Cartoned Bottles, More or Less, Sudden Change, 409 F.2d 734 (2d Cir. 1969). Thus, the Agency's regulation quoted above simply codifies the statute.

Therefore NNFA is incorrect in saying that "the drug classification rationale relied on ... by the Commissioner has since been invalidated by the new vitamin and mineral legislation" (Brief, p. 32). To say, as the Amendments do, that a food for special dietary use supplies a special dietary need that exists by reason of disease (21 U.S.C. 350(c) (3) (A)) is quite different from representing that the food will "prevent" disease.

We are dealing here, not with a right of commercial speech, but with statutory definitions. Thus, Bates v. State Bar of Arizona, 97 S.Ct. 2691 (1977), and other cases cited by NNFA (Brief, p. 33) do not apply. Under the Act, a product that "prevents" disease is a drug; a product that supplies a special dietary need that exists by reason of disease is a food. This section of the regulation is lawful.

7. The Dietary Supplement Regulations Properly Require Separate Ingredient Listing On The Label.

X (Section 105.85(i) and (j) (§ 80.1(i) and (j), Ad., pp. 25, 3d column and 26, 1st column) prescribes the manner of listing ingredients on the label of dietary supplements. Subsection (i) requires a listing of vitamins and minerals on the principal display panel or the information panel.^{20/} Subsection (j) requires a separate list of all ingredients (including vitamins and minerals) used in the

^{20/} "Principal display panel" and "information panel" are defined in footnote 19, supra.

manufacture of the product. NNFA claims that this is inconsistent with the Amendments (Brief, pp. 34-37). As shown above (pp. 37-38), this dual listing is codified by the Amendments in Section 411(b) (2) (A) of the Act (21 U.S.C. 350(b) (2) (A)) and is consistent with the Agency's regulation on ingredient labeling, 21 CFR 101.4. The statute specifically provides that "to the extent that compliance with (the proscription against listing non-vitamin or mineral ingredients on the principal display panel or the information panel) is impracticable or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary." Accordingly no "remedy" is required from the Court.

8. FDA Has Complied With The
Remand Instructions Of This Court.

NNFA alleges that the Agency erred in the conduct of the remand directed by this Court (Brief, pp. 37-44). NNFA's five instances will be treated in order.

(A) Essential Nutrients. The 1973 regulations prohibited the addition of dietary supplements of vitamins and minerals recognized as essential in human nutrition but for which no U.S. RDA's had been established (§ 125.1(c)). The 1973 regulations also prohibited these nutrients from being sold separately as foods (§ 80.1(b) (1) and (2) and (f) (1)). The Court enjoined these provisions and ordered the Agency to integrate such nutrients into the regulatory scheme (504 F.2d at 786-787).

The current regulations (§ 105.85(c) (1) and (4) and (e) (§ 80.1(c) (1), Ad., p. 23, 3d column, and (4) and (e), Ad., p. 24, 1st column)) permit vitamins and minerals which are essential or probably essential for human nutrition but for which no U.S. RDA's have been established to be included in non-conforming multivitamin dietary supplements^{21/} or single ingredient vitamin and mineral preparations. NNFA

^{21/} "Nonconforming" multivitamin dietary supplements may combine vitamins and minerals (including nutrients listed in § 105.85(c) (4) (§ 80.1(d) (4), Ad., p. 24, 1st column) that are recognized as essential or probably essential in human nutrition but for which no U.S. RDA's have been established) in combinations and maximum amounts other than those prescribed in § 105.85(d) (1) (§ 80.1(d) (1), Ad., p. 24, chart).

incorrectly reads the regulations when it alleges otherwise (Brief, pp. 37-39).

These vitamins and minerals are only excluded from standardized multivitamin preparations ^{22/} for reasons stated by the Commissioner in the May 28, 1975 Federal Register (Ad., p. 3, 2d column):

However, on the basis of scientific knowledge presently available to him and contained in the record, the Commissioner concludes that a standard of identity for multicomponent dietary supplements of vitamins and/or minerals, consumed by individuals who wish to assure themselves that they consume the range of vitamins and/or minerals important for good nutrition, does not properly encompass vitamins and minerals for which no NAS-NRC RDA nor any U.S. RDA has been established. While there is evidence that these nutrients are "essential", there currently is no body of scientific evidence establishing that American diets are deficient in any of them. Accordingly, it would be wasteful and misleading to include them in standardized multicomponent dietary supplements consumed by individuals who wish to assure themselves that they consume the range of vitamins and/or minerals important for good nutrition. Under these circumstances, the Commissioner concludes that it would not promote honesty and fair dealing in the interest of consumers for him on his own initiative to provide for the addition of such nutrients to multicomponent supplements.

Thus the regulations were amended in a way that was responsive to the Court and protective of the consumer.

(B) Criteria for Modification of the Standard of Identity. The 1973 regulations only provided for the amendment of the list of permissible combinations of vitamins and/or minerals (§ 80.1(a)(4)). This Court directed FDA to modify this subsection to permit upward revisions in the maxima for particular vitamins and minerals and to broaden the criteria for determining the appropriateness of making an amendment to conform to Section 401 of the Act (21 U.S.C. 341) (504 F.2d at 785). The Agency has done so in Section 105.85(a)(5) (§ 80.1(a)(5), Ad., p. 23, 2d column), using the criterion of Section 401 of the Act to "promote honesty and

^{22/} "Standardized" multivitamin dietary supplements contain either all vitamins and minerals, or all vitamins, or all minerals, or all vitamins and the mineral iron, listed in § 105.85(d)(1) (with the permissible omission of any vitamin or mineral defined as optional) in a specified daily quantity not less than the lower limit and not more than the upper limit of any nutrient specified in § 105.85(d)(1).

fair dealing in the interest of consumers." Contrary to NNFA (Brief, pp. 39-41), this was exactly what the Court required. It should be noted, however, that the scope of this subsection has been narrowed by the Amendments; it now applies only to standardized preparations.

(C) Iron in the Food Supply. The 1973 regulations provided that a food which purports or is represented to be a food for special dietary use is misbranded if its labeling bears any statement that represents, suggests or implies that a balanced diet of ordinary foods cannot supply adequate amounts of nutrients (§ 125.2(b)(2)). The Court upheld this provision but directed the Agency on remand to "either adduce further evidence on this point, or, as might be preferable, insert a proper qualification in (the subsection)" (504 F.2d at 802). The Agency inserted a qualification using Finding of Fact Number 45 (38 F.R. 20715 (August 2, 1973)):

Representations may be made that it is often impractical to supply the iron requirements of infants, children, and women of childbearing age with a diet of conventional foods. (105.60(b)(3), Ad., p. 27, 3d column)

Contrary to NNFA (Brief, pp. 41-2), this provision in Section 105.60(b)(2) complies with the remand instructions of this Court.

(D) Vitamin B-6, Folic Acid, and Magnesium. NNFA alleges that it has evidence that the food supply is also inadequate with respect to levels of vitamin B-6, folic acid, and magnesium, and it contends that the qualification for iron in § 105.60(b)(2) should be expanded to include these three nutrients (Brief, pp. 42-43). The Commissioner considered the very sparse testimony in the record on this point and stated that he is not aware of any "substantial" evidence to indicate that a balanced diet of ordinary foods cannot supply adequate amounts of these three nutrients (Ad., p. 21, 1st column). This conclusion of the Commissioner should not be altered unless it is clearly wrong.

(E) Natural and Synthetic Vitamins. Section 105.60(b)(6) (§ 125.2(b)(6), Ad., p. 27, 3d column)) proscribes labeling that represents, suggests, or implies "that a natural vitamin in a food is superior to an added or synthetic vitamin, or that there is a difference between vitamins naturally present and those that have been added." This provision was upheld by this Court (504 F.2d at 805).

NNFA claims that new evidence demonstrates that there is a "difference" between the natural and synthetic forms of vitamin K, and that FDA should insert a qualifying provision regarding that vitamin to this subsection (Brief, pp. 43-44). But even if there is a difference in vitamin K forms, there is no need to amend the regulations. As this Court stated in its earlier review of these regulations, "It has long been settled that an agency may adopt a rule shown to be appropriate for the generality of instances and leave the correction of injustices to applications by those concerned" (504 F.2d at 784).

9. Food Additive Restrictions
Apply To Dietary Supplements.

Section 105.85(f)(8) (§ 80.1(f)(8), Ad., p. 24, 3d column)) states that a vitamin or mineral ingredient in a dietary supplement that is not generally recognized as safe (GRAS) is a "food additive" within the meaning of Section 201(s) of the Act (21 U.S.C. 321(s)), and pursuant to Sections 402(a)(2)(C) and 409 of the Act (21 U.S.C. 342(a)(2)(C) and 348), such use is illegal in the absence of a food additive regulations approving the use.

NNFA contends that because this provision was not part of the remand instructions of the Court, it should be deleted (Brief, pp. 44-47). But NNFA admits (Brief, p. 45) that this cross reference is implicit in the general cross reference provision of § 105.85(a)(4) (§ 80.1(a)(4), Ad., p. 23, 2d column).

Further, the Conference Report explaining the effect of the Amendments specifically confirms that a vitamin or mineral that is not GRAS for inclusion in a dietary supplement is properly regulated as a food additive:

Similarly, if any vitamin, mineral or other food ingredient is not generally recognized as safe by qualified experts and meets the other criteria of the definition of a food additive under section 201(s) of the act, it would be subject to regulation under section 409 of the act (At 28).

A listing of some of the vitamins, minerals and compounds with vitamin and/or mineral properties which are generally recognized as safe, and thus lawful for use without a food additive regulation, appears at 21 CFR 185.5013. Further, numerous food additive regulations have been promulgated in Part 172 of the Code of Federal Regulations to authorize the use of certain vitamin/mineral ingredients, which are food additives, in dietary supplements. Accordingly, food additive restrictions apply to dietary supplements.

10. The Regulatory Provisions Concerning
Expiration Dating For Dietary
Supplements Are Valid.

Section 105.85(1) (§ 80.1(1)) provides that a dietary supplement containing one or more nutrients subject to deterioration below the labeled value before consumption shall contain an expiration date selected on the basis of tests to show that the dietary supplement, until that date, will contain not less than the quantity of each such vitamin and/or mineral set forth on its label. This provision assures that a product will be what it is represented to be on the label; to do otherwise would violate Section 403(a) of the Act (21 U.S.C. 343(a)). NNFA's contentions to the contrary are spurious (Brief, pp. 47-48).

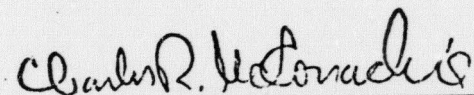
CONCLUSION

The Agency has complied with the remand instructions of this Court, the requirements of Section 553 of the Administrative Procedure Act and the

1976 Vitamin and Mineral Amendments in promulgating these revised final regulations for vitamin and mineral supplements sold as foods. The regulations should be sustained.

Respectfully submitted,

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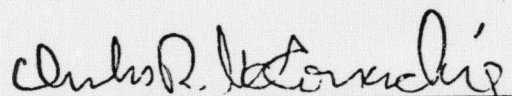
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Washington, D.C. 20530

CERTIFICATE OF SERVICE

I hereby certify that true and correct copies of the foregoing
brief, together with copies of the following addendum thereto, was served
by United States Mail, postage prepaid, this 12th day of October, 1977,
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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Parts 80, 125]

FOOD FOR SPECIAL DIETARY USES

Opportunity for Filing Applications for Additional Formulations of Dietary Supplements of Vitamins and Minerals; Preliminary Notice of Reopening of Hearing; Tentative Amendments to Final Orders

In the FEDERAL REGISTER of August 2, 1973 (38 FR 20703, 20730), the Commissioner of Food and Drugs established new regulations to govern the labeling of foods for special dietary uses in §§ 125.1, 125.2 and 125.3 (21 CFR 125.1, 125.2, 125.3) and to govern the composition of dietary supplements of vitamins and minerals in § 80.1 (21 CFR 80.1). Subsequently, 15 petitions for review of these regulations were filed in various United States courts of appeals, and all petitions were eventually consolidated in the United States Court of Appeals for the Second Circuit. After extensive briefing and argument, that Court rendered judgment on August 15, 1974. "National Nutritional Foods Association v. Food and Drug Administration," 504 F.2d 761 (2d Cir. 1974). While the Court stated that it was "broadly sustaining the regulations," it nevertheless remanded the regulations to the Food and Drug Administration for certain specified action and stayed the effective date of the regulations "until six months after our judgment becomes final or June 30, 1975, whichever is later". (504 F.2d 785-786.) A copy of this judgment is on file with the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852.

On February 24, 1975, the Supreme Court denied certiorari in this case. Accordingly, the Commissioner concludes that it is now appropriate to develop revised regulations, in compliance with the directions of the Court of Appeals, as expeditiously as is feasible.

I. APPLICATIONS FOR ADDITIONAL FORMULATIONS

The Court's decision directs the Commissioner to receive and consider applications for additional formulations of dietary supplements.

The Commissioner hereby invites applications from any interested persons who desire that additional formulations of dietary supplements of vitamins and/or minerals be permitted under § 80.1 (21 CFR 80.1). Applications may be filed for additional combinations of vitamins and/or minerals and/or for increased potency of any vitamins or minerals within a combination. An additional formulation incorporating a substance or potency that is not generally recognized as safe shall also require a food additive petition pursuant to sections 201(s), 402(a)(2)(C), and 409 of the act (21 U.S.C. 321(s), 342(a)(2)(C), 348).

A separate application shall be filed with the Hearing Clerk, in quadruplicate, for each formulation sought. Each application shall include:

a. A description of the formulation sought, containing a list of all vitamins and/or minerals to be included, the potency of each, and an explanation of how the formulation differs from those presently authorized by 21 CFR 80.1, together with the name proposed by the applicant for such formulation.

b. A statement of the nutritional or other physiological rationale, if any, which the applicant believes justifies the formulation. One or more affidavits by qualified experts, and/or copies of published scientific literature in support of any such rationale shall be included.

c. A statement of any other rationale which the applicant believes shows a need for the formulation. If an existing consumer demand or market for the formulation is asserted on behalf of the product, the applicant shall include copies of labeling for the existing product, including labels, cartons, leaflets, etc., and an affidavit(s) with accompanying documentation establishing the scope of the existing market, including data on the number of units sold and the wholesale and retail value involved.

All applications shall be received by the Hearing Clerk, Food and Drug Administration, not later than close of business on or before July 14, 1975. Applications received after that date will be held in abeyance pending review after all other issues relating to this matter are disposed of.

In evaluating the applications the Commissioner will be guided by the following statement by the Court:

The FDA should establish dates for the filing of such applications and, if these should prove to be numerous, procedures to screen out the most meritorious for early hearing and decision. In determining whether it is "reasonable" to deny a particular application, the primary consideration must of course be the degree of increase in potential consumer confusion. Since the sheer variety of products is a central problem here, the applications will in a real sense be in competition with one another, and we do not expect a very large number to be granted. It would be reasonable in resolving this competition to favor products which, because of widespread prior publicity or even just because of simplicity of terminology, are unlikely to confuse many consumers when properly labeled. Indeed, we specifically direct that the FDA consider any such applications as to vitamin C in larger dosages and vitamin B complex supplements. Moreover, against any danger of slight increases in confusion should be weighed such factors as the following: (1) How large is the consumer demand for the product at present, and how widespread any expert belief that it is not an irrational product for a significant number of consumers; (2) how effectively could any potential confusion with respect to the particular product be reduced or eliminated by requiring on the label (A) with respect to a high dosage product, a legend to the effect that the FDA has determined this product contains quantities of such-and-such nutrients not normally essential to human health, or (B) with respect to a combination, a legend to the effect that the FDA has determined this product does not contain all the nutrients essential to human health, and (3) in the case of application to exceed the upper limits, how dependable, if this can be determined, is the particular NAS RDA on which the upper limit is based rela-

tive to other RDA's . . . We wish to make clear, that, while it would defeat the purposes of Part 80 for a very large number of such applications to be granted, either with respect to dosage limitations or with respect to combinations of less than all essential ingredients, we expect each application to receive the most serious consideration on its merits relative to the criteria just outlined. At the same time it is to be obvious to the petitioners that we are broadly sustaining the regulations and that any attempt to convert the procedures we are here directing into something like a nearly complete reopening of the proceeding will be counter-productive. Indeed, if an avalanche of petitions for exceptions should occur, the agency would be justified in denying all applications (except those as to increased dosages of vitamin C and vitamin B complex supplements), without prejudice to subsequent renewal, on this ground alone. What we are doing is to provide the industry with another chance of individualized consideration of the most meritorious cases of exceptions. An exercise of responsibility on the part of the industry will be necessary if this is to confer the benefits we intend. (504 F.2d 785-786.)

The Commissioner advises that it will not be necessary for anyone to file an application for the high potency vitamin C product mentioned by the Court or for any other high potency product composed of a single vitamin or mineral. As set forth in section III of this notice, the Commissioner is tentatively amending the final orders so that Parts 80 and 125, which establish a standard of identity and labeling requirements, will impose no potency limitations on products consisting of a single vitamin or mineral. Limitations for reasons of safety may be imposed by other regulations in Part 121 and in other sections in this chapter or by direct application of the act, as discussed in section III.h. of this preamble.

As explained in section III.h. below, new information may be developed by the GRAS Review Project or the OTC Drug Review concerning the toxicity of particular vitamins and/or minerals which would cause the Food and Drug Administration either to propose new restrictions in the interest of public safety or to propose elimination of certain existing restrictions as no longer justified.

The Commissioner is trusting industry to exercise restraint and common sense in restricting itself to applications with some legitimate basis and hopes that it will not be necessary to respond to an "avalanche" of applications with the sanction suggested by the Court in the passage quoted above. The Commissioner requests that the affected industries consolidate their interests and file joint applications, documented in the manner set forth above, for a small number of additional formulations.

II. PRELIMINARY NOTICE OF REOPENING OF HEARING

The Court's decision remanded the regulations to the Agency "with instructions to reopen the record for the limited purpose of permitting reasonable cross-examination of Dr. [William H.] Sebrell (or, if he is not available, some

other qualified member of the (Food and Nutrition) Board (of the National Academy of Sciences) by Dr. (Miles) Robinson or counsel of some other similarly Interested Participant". [504 F. 2d 799.]

Dr. Sebrell is no longer a member of the Food and Nutrition Board. Tentative arrangements have been made to call instead Dr. Alfred E. Harper, who was Dr. Sebrell's successor as the Chairman of the Committee on Dietary Allowances of the Food and Nutrition Board, serving in that capacity at the time of development and publication of the most recent (eighth) edition (1974) of the National Academy of Sciences-National Research Council's "Recommended Dietary Allowances." Dr. Harper is Professor of Nutrition Sciences and Biochemistry and Chairman of the Department of Nutritional Sciences, University of Wisconsin. Dr. Harper will not tender any direct testimony on behalf of the Government except to identify and provide for the record a copy of the eighth edition (1974) of the "Recommended Dietary Allowances" developed by the Food and Nutrition Board of the National Academy of Sciences-National Research Council. (The seventh edition (1968) of this publication was one of the fundamental sources relied upon in the development of Parts 80 and 125. The eighth edition was published after appellate review of these regulations had begun. Since the eighth edition was cited and quoted in briefs before the Court of Appeals and the Court itself referred to the eighth edition in its decision [504 F.2d 791, 798, 799 (Fint. 67)], it seems clear that a copy of the publication in its entirety should be included in the record prior to the commencement of the examination of Dr. Harper.) Instead, pursuant to the Court's direction, he will be available as Dr. Sebrell's successor to respond to inquiry by those opposed to the regulations, concerning (1) the methodology employed in development of the recommended dietary allowances by the Board and the scientific foundation upon which these allowances are based, (2) the scientific appropriateness of the Food and Drug Administration's use of the Board's recommended dietary allowances, and (3) possible biases or conflicts of interests on the part of the Board, as well as other relevant subjects.

The Commissioner intends to issue shortly in the FEDERAL REGISTER a notice announcing a specific time and place for reopening of the hearing for examination of Dr. Harper. At that time new notices of appearance will be required for all who wish to participate since it is likely that some of the participants of record may have changed their address or their counsel or may no longer wish to participate, and the Commissioner believes the proceeding should be open to new persons who are not presently participants of record.

It is the Commissioner's intention that this proceeding take place in the Hearing Room at the Food and Drug Administration headquarters in Rockville, MD.

While the Court has required only that

Dr. Robinson or counsel of some other similarly interested participant be allowed to engage in examination, the Commissioner intends that the examination be open to as many participants reflecting as many points of view as is reasonably possible. (Indeed, such an open approach appears necessary to avoid a conflict concerning the person to conduct cross-examination. At the time of the hearing, Dr. Robinson was the official representative of the National Health Federation (NHF). It appears that Dr. Robinson is no longer acting for the NHF and that both Dr. Robinson and the NHF may assert a claim to conduct the cross-examination envisioned by the Court.)

The Commissioner will direct the Administrative Law Judge that, if requests to engage in examination are numerous and the participants cannot agree among themselves on apportionment of time or subject matter sufficient to accommodate all within a reasonable period of time, he should group participants with truly common interests and allow only one, or perhaps a few, qualified representative(s) from each group to examine Dr. Harper.

The Administrative Law Judge will be directed to expedite his report to the Commissioner upon concluding the hearing.

III. TENTATIVE AMENDMENTS TO FINAL ORDERS

Having carefully considered the decision of the Court of Appeals, the Commissioner concludes that a number of revisions, discussed below, should be made in the regulations.

a. *Elimination of maximum potency restrictions on dietary supplements consisting of a single vitamin or mineral.* Section 80.1(c) (1) is tentatively amended below to eliminate any maximum potency limitations on dietary supplements consisting of a single vitamin or mineral. (As discussed below in paragraph III.h. of this notice, potency may be restricted for reasons of safety by other sections of the act not here involved or by other regulations.)

The Commissioner remains convinced that, in the case of multicomponent supplements, consumed by individuals who wish to assure themselves that they consume the range of vitamins and/or minerals important for good nutrition, the vitamins and/or minerals included should be present in potency ranges generally recognized by qualified experts to be appropriate for such purposes, reflecting reasonable balances among the vitamins and/or minerals. The concept of standardized multicomponent supplements is that they provide essential vitamins and/or minerals which are useful for supplementation purposes (i.e., those which are not only essential to good health but for which there is a reasonable possibility of dietary deficiency) at levels that are nutritionally useful and that maintain reasonable balance among the vitamins and/or minerals. In the Commissioner's judgment, such combination products should not provide excessive quantities of a vitamin or mineral

which are wasteful, i.e., nutritionally useless and immediately excreted out of the system, and which serve only to create consumer confusion leading to false bases of comparison and competition between products, which may lead to higher prices but not to better products. Pursuant to the tentative amendment, on the other hand, dietary supplements consisting of a single vitamin or mineral may be marketed whether or not there is a nutritional rationale for such supplementation at potencies in excess of any established nutritional usefulness. The Commissioner concludes that this approach preserves the nutritional integrity of the multicomponent dietary supplements while assuring the public that dietary supplements consisting of a single vitamin or mineral will be available individually with no upper limits except those dictated by safety.

b. *Status of vitamins and minerals for which there are no U.S. RDA's.* With regard to dietary supplements of vitamins and/or minerals, the decision of the Court enjoins the provisions of § 125.1 (c) which had prohibited the addition of certain vitamins and minerals recognized as essential in human nutrition but for which no U.S. Recommended Daily Allowances (U.S. RDA's) have been established and which had prohibited the addition of such vitamins and minerals to general purpose foods. The Court also directed the Agency to consider whether there are other essential nutrients for which no U.S. RDA's have been established, which are unmentioned in the present regulations and which should be added. The Court specifically mentioned cobalt and selenium for consideration.

Pursuant to the Court's decision, § 125.1(c) is tentatively amended below to become simply an informational paragraph. It lists those vitamins and minerals which are essential or probably essential in human nutrition but for which no U.S. RDA's have been established. The list has been expanded to include all additional vitamins and minerals which the Food and Nutrition Board of the National Academy of Sciences-National Research Council (NAS-NRC) has concluded are essential nutrients, or probably essential nutrients for man but for which the NAS-NRC has established no recommended dietary allowances and for which, consequently, no U.S. RDA's have been established. As tentatively amended, the list now includes two vitamins, i.e., vitamin K and choline, and twelve minerals, i.e., chlorine, chromium, fluorine, manganese, molybdenum, nickel, potassium, selenium, silicon, sodium, tin and vanadium.

The Commissioner concludes that cobalt should not be added to § 125.1(c). Cobalt per se is not an essential nutrient. Its only known function is as an integral part of vitamin B₁₂ (cobalamin), which is already included in the list of mandatory essential vitamins. Therefore, there is no basis for including cobalt in § 125.1 (c). In any event, cobalt is not generally recognized as safe for use in food and thus any food use is illegal in the absence of a supporting food additive regulation.

(21 U.S.C. 321(s), 342(a)(2)(C), 348.) Because of toxicity, 21 CFR 121.106(d) (9), published in the FEDERAL REGISTER of September 23, 1974 (39 FR 34172), specifically prohibits any food use of cobaltous salts.

Sulfur has been deleted from § 125.1(c) as tentatively revised because sulfur per se is not an essential nutrient but rather an integral part of the molecular structure of several amino acids (methionine, cystine, cysteine). The concept of sulfur being referred to as an essential nutrient stems from this fact. Sulfur involved in metabolic processes other than protein synthesis is derived in fully adequate amounts from the normal degradation of proteins containing the sulfur amino acids. Dietary sulfur in the form of various salts makes no contribution to the metabolic function of sulfur in the body. Sulfur may lawfully be sold as an ordinary food in any compound which is generally recognized as safe, if there is anyone interested in buying of selling such a product. (Several sulfur compounds which are generally recognized as safe and thus lawful for use without a food additive regulation, 21 U.S.C. 321(s), 342(a)(2)(C), 348, are listed in 21 CFR 121.101(d).) However, any representation that such sulfur is a dietary supplement or that it has special dietary properties would be false or misleading and unlawful.

For many of the substances included in § 125.1(c) as tentatively revised, it is unlikely that NAS-NRC RDA's or U.S. RDA's will ever be established. For example, while nickel appears to be essential to good health as determined by experimental animal studies, the needed level of intake is so low and natural environmental availability is so pervasively abundant that there is no prospect of any dietary insufficiency and no need to divert research resources to determining a specific NAS-NRC RDA or U.S. RDA for humans.

The decision of the Court of Appeals also directs that all essential vitamins and minerals for which no U.S. RDA's have been established be integrated into § 80.1(b)(1)(v) and into the list of optional nutrients in § 80.1(f) until such time as U.S. RDA's may be established. The Commissioner is tentatively amending the regulations in a manner which he believes is responsive to the intentions of the Court.

The Court was concerned about the lack of support for the banning from sale of safe amounts of essential nutrients for which U.S. RDA's have not been established. The Commissioner accordingly concludes that the regulations should be amended to add to § 80.1 a new paragraph (f)(3) to recognize and list other vitamins and minerals, unlisted in § 80.1(f)(1), which are recognized as essential, or probably essential, in human nutrition but for which no U.S. RDA's have been established. (This is the same list of nutrients which appears in tentatively amended § 125.1(c), as discussed above.)

Because § 80.1(b)(2) provides that a dietary supplement may be composed of any single vitamin or mineral listed in

§ 80.1(f), the effect of new § 80.1(f)(3) is that a dietary supplement consisting of a single vitamin or mineral for which no U.S. RDA has been established may be sold without any restrictions on potency imposed by Part 80 or 125. (As discussed in paragraph III.h. of this preamble, availability may be restricted for reasons of safety by other sections of the act not here involved or by other regulations.)

However, on the basis of scientific knowledge presently available to him and contained in the record, the Commissioner concludes that a standard of identity for multicomponent dietary supplements of vitamins and/or minerals, consumed by individuals who wish to assure themselves that they consume the range of vitamins and/or minerals important for good nutrition, does not properly encompass vitamins and minerals for which no NAS-NRC RDA nor any U.S. RDA has been established. While there is evidence that these nutrients are "essential", there currently is no body of scientific evidence establishing that American diets are deficient in any of them. Accordingly, it would be wasteful and misleading to include them in standardized multicomponent dietary supplements consumed by individuals who wish to assure themselves that they consume the range of vitamins and/or minerals important for good nutrition. Under these circumstances, the Commissioner concludes that it would not promote honesty and fair dealing in the interest of consumers for him on his own initiative to provide for the addition of such nutrients to multicomponent supplements.

In section I of this preamble, the Commissioner invites the filing of applications for additional formulations of dietary supplements of vitamins and minerals. The Commissioner advises that he will give unbiased consideration to any application which concerns additional multicomponent combinations involving vitamins and/or minerals for which no U.S. RDA has been established, and he recognizes his obligation under the decision of the Court to consider permitting a limited number of additional formulations under the conditions established by the Court.

Finally, the Commissioner has concluded that dietary supplements of vitamins and/or minerals containing a vitamin(s) or mineral(s) for which no U.S. RDA has been established should bear a statement to inform the consumer of this fact. Sections 80.1(d)(1) and 125.3(a)(2) are tentatively amended to require label statement of such information.

c. *Elimination of provision that high potency vitamin/mineral products are drugs.* The Court ruled § 125.1(h) to be invalid. This paragraph had provided that, except for certain specified and quite limited products, a vitamin/mineral product with a potency exceeding the limits set by § 80.1 was necessarily a drug.

The Court concluded that the hearing record did not show that there is no

known food use of nutrients at such high levels.

• • • It cannot be said even as an objective matter that a given bottle of pills, each containing more than the upper limit of one or more nutrients, is not being used for nutritional purposes.

A fortiori: It follows that the vendor of such a product can in good faith intend it for nontherapeutic use. Section 201(f)(1)(B) [21 U.S.C. 321(f)(1)(B)] makes the vendor's intent the crucial element in the definition of "drug" here at issue • • • while we agree that a factfinder should be free to pierce all of a manufacturer's subjective claims of intent and even his misleadingly "nutritional" labels to find actual therapeutic intent on the basis of objective evidence in a proper case, such objective evidence would need to consist of something more than demonstrated uselessness as a food for most people • • •

Our invalidation of this subsection in no way prevents high-dosage products properly labeled from being marketed as over-the-counter drugs. But under our ruling § 125.1(h) will cease to have any independent restrictive force. [504 F.2d 769.]

The Commissioner has considered whether the record should be reopened to permit the admission of additional evidence on this matter. In view of the fact that the sole difference between the approach taken in § 125.1(h) and the approach taken by the Court is that, pursuant to the Court's decision, these products will now be regulated under the law as foods rather than as over-the-counter (nonprescription) drugs, the Commissioner has concluded that no useful purpose would be served by pursuing this point as a general rule at this time. It is now clear that, in specific situations involving an individual vitamin or mineral, where the need for prescription drug control is essential to protect the public health, the vitamin or mineral in question may properly be classified as a prescription drug to prevent indiscriminate use by laymen without medical supervision. See "National Nutritional Foods Association v. Weinberger," No. 74-1738 (2d Cir. 1975). Accordingly, pursuant to the Court's decision, the tentative order revokes § 125.1(h).

As the foregoing quotation from the Court's decision specifically recognizes, a person may choose to offer a vitamin and/or mineral product as a drug rather than as a food, in which case the product must comply with the drug requirements of the act and the regulations promulgated pursuant thereto rather than these regulations.

The term "dietary supplement" applies solely to foods and has no application to a product offered solely as a drug. A vitamin and/or mineral product which is offered as a food and which comes within the definition of a "dietary supplement" in Part 80 must, of course, comply with the definition and standard of identity established by Part 80. Section 403(g) of the act (21 U.S.C. 343(g)) provides that a food shall be deemed to be misbranded if it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulation unless it conforms to such definition and standard.

A new § 80.1(n)(1) is added to the regulations to explain that a dietary supplement which does not comply with the standard of identity for dietary supplements will be deemed to be a misbranded food pursuant to section 403(g) of the act.

d. *"Unmentioned elements."* The Agency was directed by the Court "to articulate its intentions with respect to those unmentioned elements which it finds not to be essential".

Ingredients which have in the past been represented as having nutritional properties but which have not been shown to be essential in human nutrition and thus are not included in § 125.1 will continue to be governed by the provisions of § 125.2(b)(5), i.e., they may not be added to vitamin/mineral supplements but they may be sold as ordinary foods by themselves or in combination with one another. Thus, for example, a person remains free to sell rutin tablets, or tablets containing a combination of rutin and para-amino-benzoic acid, etc., as food provided no claims are made for such foods to the effect that they have special nutritional properties. However, one may not add rutin or para-amino-benzoic acid to a vitamin and/or mineral supplement because to do so would tend to mislead a consumer into believing that the additional ingredient makes the supplement more useful.

Section 125.2(b)(5) presently lists specific substances which have in the past been represented as having nutritional properties but which have not been shown to be essential to human nutrition e.g., rutin, para-amino-benzoic acid. The substances included by name in § 125.2(b)(5) are automatically banned by operation of law from vitamin and/or mineral supplements by § 125.2(b)(5). To rely on this section of the regulation for banning any other such substance from a vitamin and/or mineral supplement, it would be necessary either (1) to demonstrate by an appropriate factual showing that the substance has been represented as having nutritional properties but has not been shown to be essential in human nutrition, and that it is thus within the class of substances banned from dietary supplements by 21 CFR 125.2(b)(5), e.g., in a civil seizure action pursuant to section 304 of the act (21 U.S.C. 334), or (2) to engage in new rule making to add the substance, by name, to § 125.2(b)(5).

Under the regulations, it is not permissible to add to a dietary supplement any ingredient which does not provide a vitamin or mineral or serve a functional purpose, since the definition and standard of identity does not provide for the inclusion of such substances. (21 CFR 80.1(g); 21 U.S.C. 343(g)(1).) Thus a substance which does not provide any vitamin or mineral and which is not a "preservative, stabilizer, flavor, sweetener, color, seasoning, carrier, base, or vehicle" and which does not "facilitate preparation" of the vitamin and mineral substances, may not be included in a dietary supplement. (21 CFR 80.1(g); 21 U.S.C. 343(g)(1).)

Of course, even if a substance may legally be included in a dietary supplement of vitamins and minerals, it may not be declared on the label in a manner which is false or misleading or otherwise in violation of the act or regulations. For example, assuming that alfalfa is a source of vitamin A activity, the regulations would permit use of alfalfa as the source of vitamin A in the manufacture of a dietary supplement of vitamin A. Such a product would be labeled as a "vitamin A supplement" (21 CFR 80.1(h)), and "alfalfa" would be included in the list of ingredients (21 CFR 80.1(i)(4)), but not in the listing of vitamins and minerals (21 CFR 80.1(i)(1)). It would also be permissible to include in labeling for such a dietary supplement of vitamin A a truthful statement that it is "derived from alfalfa". However, to offer such a product as a "vitamin A—alfalfa supplement" would violate 21 CFR 80.1(h) and section 403(a) of the act (21 U.S.C. 343(a)). A product such as "powdered alfalfa" could be sold as an ordinary food, rather than as a dietary supplement, with nutrition labeling pursuant to 21 CFR 1.17.)

Of course, any unqualified representation in labeling of a special dietary food to the effect that the vitamin or mineral content is derived from a particular source would be misleading, in violation of sections 403(a) and 201(n) of the act (21 U.S.C. 343(a), 321(n)), unless that source provides a significant portion of the vitamin or mineral content of the product. For example, it would be misleading for a dietary supplement to bear labeling claims such as "vitamin A derived from alfalfa" or "vitamin C derived from rose hips", if only two percent of the vitamin A, or vitamin C, content of the product is derived from that source.

To help clarify this situation and prevent misleading labeling with regard to the source of a vitamin or mineral, a tentative amendment to the regulations, 21 CFR 125.3(c), requires that whenever a representation is included in labeling concerning the source of a vitamin or mineral, the representation shall be accompanied, in type of at least equal size and prominence, by a statement of the percent of the vitamin or mineral content provided by that source. For example, if 40 percent of the vitamin A content of a dietary supplement is derived from alfalfa, a label statement "contains vitamin A derived from alfalfa" would be required to be accompanied, in type of equal size and prominence, by a statement such as "40 percent of the vitamin A content of this product is derived from alfalfa".

e. *Certain representations concerning iron.* Pursuant to the Court's decision, § 125.2(b)(2) is amended to permit representations that infants, children, and women of childbearing age may not be receiving adequate amounts of iron in their daily diets.

f. *Revisions in formulations.* As directed by the Court, § 80.1(b)(4) is amended to make clear that future revisions regarding permissible formulations might involve greater product potencies as well as different combinations

of ingredients, when such revisions would promote honesty and fair dealing in the interest of consumers.

g. *Fresh fruits and vegetables.* Section 80.1(e)(5) and (6) is amended to implement the Court's order that fresh fruits and fresh vegetables be exempted from the regulations. In a notice published in the Federal Register of February 26, 1975 (40 FR 8214), the Commissioner proposed regulations to govern nutrition labeling of fresh fruits and fresh vegetables.

h. *Safety restrictions imposed by other regulations or by the act.* Although Parts 80 and 125, as tentatively amended, do not place any restriction upon the potency of a vitamin or mineral sold individually, restrictions on maximum potency or other restrictions on availability or use may be imposed for reasons of safety by other regulations or by the act. For informational purposes, pertinent restrictions are cross-referenced in tentative new § 80.1(n)(2).

A discussion of existing limitations on food use of vitamins and minerals imposed by other regulations and cross-referenced for informational purposes in new § 80.1(n)(2) follows:

(1) *Vitamin A.* Any oral preparation containing vitamin A in excess of 10,000 IU per dosage unit or recommended daily intake is deemed to be a drug and is restricted to prescription sale (21 CFR 250.109). Sale of a product exceeding this potency as a dietary supplement would be illegal.

(2) *Vitamin D.* Any oral preparation containing vitamin D in excess of 400 IU per dosage unit or recommended daily intake is deemed to be a drug and is restricted to prescription sale (21 CFR 250.110). Sale of a product exceeding this potency as a dietary supplement would be illegal. (21 CFR 250.11 contains an exception for foods which are for use under medical supervision to meet nutritional requirements of persons with poor vitamin D absorption, which may contain vitamin D not in excess of 1,000 IU per dosage unit or recommended daily intake.)

(3) *Folic acid.* Folic acid is not generally recognized as safe for addition to food for its vitamin property and consequently the substance is a food additive for such use subject to the limitations on use set forth in the food additive regulation 21 CFR 121.1134 (e.g., maximum daily adult intake not to exceed 0.4 mg except for pregnant or lactating women, for whom the limit is 0.3 mg).

(4) *Iodine.* Iodine is not generally recognized as safe for addition to food for its mineral property except when added to table salt as cuprous iodide or potassium iodide at a level not to exceed 0.01 percent (21 CFR 121.101(d)(5)). Any other addition of iodine to food for its mineral property constitutes usage as a food additive and must be in accord with a food additive regulation. Food additive regulation 21 CFR 121.1073 permits the addition of iodine to food for its mineral property if contributed as potassium iodide, with certain restrictions (e.g., maximum daily adult intake not to exceed 225 mcg except for pregnant or

lactating women, for whom the limit is 300 mcg). Food additive regulation 21 CFR 121.1149 permits the addition of kelp to food as a source of iodine, with the same potency restrictions.

(5) **Copper.** Copper gluconate as copper gluconate is not generally recognized as safe for addition to food for its mineral property if the copper gluconate exceeds 0.005 percent by weight of the finished food product (21 CFR 121.101(d)(5)). Use of copper gluconate in a dietary supplement in excess of this level is illegal in the absence of a food additive regulation approving such use.

(6) **Fluorine.** Because of the potential toxicity of fluorine compounds, fluorine is not generally recognized as safe for addition to food, except for low levels in water as approved by the Public Health Service (21 CFR 121.10). Accordingly, in the absence of an authorizing food additive regulation, the inclusion of fluorine in a dietary supplement product would be illegal.

(7) **Potassium.** Preparations of potassium salts providing 100 mg or more of potassium per tablet (or 20 mg or more per milliliter) are deemed to be drugs and are restricted to sale on a prescription basis by § 201.306 (21 CFR 201.306) because concentrated doses of potassium salts may produce serious and possibly fatal lesions in the small bowel.

In addition to the limitations on use of particular vitamins and minerals imposed by existing regulations, as discussed above, food use of a vitamin or mineral may be restricted for reasons of safety by direct application of the act.

Any added vitamin or mineral which is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown to be safe under the conditions of its intended use in food is a food additive within the meaning of section 201(s) of the act (21 U.S.C. 321(s)), and pursuant to sections 402(a)(2)(C) and 409 of the act (21 U.S.C. 342(a)(2)(C) and 348) such use is illegal in the absence of a food additive regulation approving such use. This legal principle is set forth in new § 80.1(n) for informational purposes.

For example, in the judgment of the Commissioner, molybdenum is not generally recognized as safe for addition to food. Thus, a "molybdenum supplement" would be subject to regulatory action, e.g., a civil seizure action in a United States District Court pursuant to section 304 of the act (21 U.S.C. 334), charging that the supplement is adulterated within the meaning of section 402(a)(2)(C) of the act (21 U.S.C. 342(a)(2)(C)) in that it contains a food additive within the meaning of section 201(s) of the act (21 U.S.C. 321(s)), i.e., molybdenum, which is unsafe for such use within the meaning of section 409 of the act (21 U.S.C. 348) because there is no food additive regulation or exemption permitting such use. Should a claimant, under these circumstances, contend that molybdenum is generally recognized as safe and thus not a food additive within the meaning of 21 U.S.C. 321(s), this would be a factual issue for determination in

the civil seizure action in the absence of a regulation governing the status of the nutrient.

A listing of some of the vitamins, minerals and compounds with vitamin and/or mineral properties which are generally recognized as safe (GRAS), and thus (since a substance which is GRAS is not a food additive, 21 U.S.C. 321(s)) lawful for use without a food additive regulation, appears at § 121.101(d)(5) (21 CFR 121.101(d)(5)).

As 21 CFR 121.101(a) specifically advises, it is not practicable to list by regulation all substances that are generally recognized as safe for their intended use. Accordingly, upon request, addressed to U.S. Food and Drug Administration, Bureau of Foods, Division of Regulatory Guidance, HFF-310, 200 C St. SW., Washington, D.C. 20204, the Food and Drug Administration will advise whether, in its judgment, a particular use of a vitamin or mineral (not specifically governed by regulation) is generally recognized as safe within the meaning of section 201(s) of the act and thus lawful for use without a food additive regulation.

Pursuant to new safety data developed by the Food and Drug Administration's GRAS Review Project, described in the FEDERAL REGISTER of July 26, 1973 (38 FR 20053), or developed by the Food and Drug Administration's Over-the-Counter (OTC, i.e., nonprescription) Drug Review, described in § 330.10 (21 CFR 330.10), or derived from other sources, additional restrictions in the interest of safety may be imposed on the use of a vitamin or mineral by appropriate new rule making, or existing restrictions may be eliminated. Restrictions contained in such regulations will routinely be cross-referenced in § 80.1(n) (2).

The Commissioner advises that he is planning to initiate new rule making to particularize more comprehensively than existing § 121.101(d)(5) the vitamins, minerals and compounds with vitamin and/or mineral properties which are GRAS (specifying potency limitations where recognition of safety depends upon such limited use) and to list as well those substances which are not GRAS at any level of use. Proposals for such rule making will appear in the FEDERAL REGISTER.

In the meantime, the Commissioner advises that he presently has the following tentative views regarding safety of nutrients not already discussed above. Except for vitamins A and D and folic acid (all three of which are subject to existing regulations restricting potency, discussed above), the Commissioner does not believe that current scientific knowledge warrants any potency restrictions in the interest of safety upon use of the vitamins (mandatory or optional) listed in § 80.1(f)(1) or upon the use of choline. However, with regard to vitamin K, the Commissioner is presently of the opinion that synthesized vitamin K (menadione) could only be intended for therapeutic use, and, because of the potential for harm involved in its use, that it should be dispensed only on prescription. The naturally occurring vi-

tamin K (phylloquinone), on the other hand, appears to be generally recognized as safe for use as a dietary supplement at least up to levels providing 100 percent recommended daily quantity. With all of the minerals included in § 80.1

(1) are generally recognized as safe use in dietary supplements at levels up to 150 percent of the U.S. RDA a day, toxicity concerns arise if higher tendencies are chronically consumed, and, practicable, it would be useful to particularize by regulation, in the forthcoming rule making, the potency levels at which these nutrients cease to be GRAS. Manganese appears to be generally recognized as safe for use as a dietary supplement for adults and children 4 or more years of age at levels of up to 1.0 mg per recommended daily quantity. Chlorine and sodium may cease to be GRAS for dietary supplement use at certain levels. Final in the absence of any reliable data existing at this time to indicate a safe level for addition to food, and in view of recognized toxic potentialities, the Commissioner has tentatively concluded that chromium, molybdenum, nickel, selenium, silicon, tin, and vanadium are not GRAS for addition to food for dietary supplementation and that any such use would require a food additive application. The foregoing observations are offered simply as a matter of information concerning the Commissioner's present tentative views on the GRAS status of particular nutrients; the forthcoming proposed rule making will include a detailed discussion of the safety concerns, if any, which arise with regard to each nutrient, together with citations to published literature.

i. **Lower limits for supplements without U.S. RDA's.** The Commissioner advises that, based on current scientific knowledge available to him, a dietary supplement providing respectively less than 200 mg of choline, 50 mg of naturally occurring vitamin K (phylloquinone), or 1.25 mg of manganese per recommended daily quantity would not serve a useful purpose as a dietary supplement. Promotion of supplements containing less than these respective amounts would be misleading, in violation of section 403(a) of the act.

j. **Future revisions of U.S. RDA's.** The United States Recommended Daily Allowances (U.S. RDA's) were established primarily on the basis of the recommended dietary allowances (RDA's) contained in the 7th edition of "Recommended Dietary Allowances," published in 1968 by the NAS-NRC. The 8th edition, published in 1974, contains a number of changes in the NAS-NRC RDA's for various age and sex groups. It is the Commissioner's present view that the changes made are not of sufficient magnitude as they relate to overall public health to warrant similar changes in the U.S. RDA's at this point in time. However, the Commissioner advises that U.S. RDA's may be prepared for additional nutrients over the next several years on the basis of accumulating scientific knowledge, and that it is reasonable to anticipate changes in existing U.S. RDA's to reflect changes in the NAS-

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NRC RDA's when the latter are next published, probably 1979.

k. *Miscellaneous.* The remaining changes implemented by the amendment to the tentative order involve adjustments for consistency with the changes already discussed.

In accordance with the foregoing discussion and pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 201(n), 401, 403 (a) and (j), 701 (a) and (e), 52 Stat. 1041, 1046-1048, 1055, 70 Stat. 919; 21 U.S.C. 321(n), 341, 343 (a) and (j), 371 (a) and (e)) and under authority delegated to him (21 CFR 2.120), the Commissioner issues the following tentative amendments to the final orders establishing §§ 80.1, 125.1, 125.2, and 125.3.

PART 80—DEFINITIONS AND STANDARDS OF IDENTITY FOR FOOD FOR SPECIAL DIETARY USES

1. Section 80.1 is amended by revising the introductory text of paragraph (b) (1), paragraphs (b) (4), (c) (1), (e) (5) and (6), (h) (2) (v) and (i) (1), and by adding new paragraphs (f) (3) and (n) to read as follows:

§ 80.1 Dietary supplements of vitamins and minerals; definition, identity, label statements.

(b) . . .

(1) A dietary supplement consisting of more than one vitamin or mineral shall contain only those vitamins and/or minerals listed in paragraph (f) (1) of this section and shall be offered for its vitamin and/or mineral content only in the following combinations, with the provision that any vitamin or mineral defined as optional in paragraph (f) (1) of this section may be omitted:

(4) Amendment of the list of permissible combinations of vitamins and/or minerals contained in paragraph (b) (1) of this section and/or of the permitted range of potency for any vitamin(s) or mineral(s) in a combination product, or any other amendments to this section, may be proposed by the Commissioner of Food and Drugs on his own initiative or upon petition by an interested person in accordance with the procedure set forth in Part 2 of this chapter. Any such petition shall be submitted in the form set forth in § 2.65 of this chapter and shall include data to show that such amendment will promote honesty and fair dealing in the interest of consumers.

(c) . . .

(1) Subject to good manufacturing practices, dietary supplements consisting of more than one vitamin or mineral shall contain in the specified daily quantity not less than the lower limit nor more than the upper limit of any nutrient specified in paragraph (f) (1) of this section for the groups for which the supplement is offered; and dietary supplements consisting of a single vitamin or mineral listed in paragraph (f) (1) of this section shall contain in the specified daily

quantity not less than the lower limit of the nutrient specified in paragraph (f) (1) of this section for the groups for which the nutrient is offered.

(e) . . .

(5) Foods to which one or more nutrient(s) listed in paragraph (f) (1) of this section are added to improve nutritional quality, unless the total level, including any naturally occurring amounts, of any such added vitamin or mineral per single serving attains or exceeds 50 percent of the U.S. Recommended Daily Allowance (U.S. RDA) for adults and children 4 years or more of age as specified in § 125.1(b) of this chapter, in which case the provisions of both this section and § 1.17 of this chapter shall apply. If the provisions of both this section and § 1.17 of this chapter apply to a food, the labeling of such food shall conform to the labeling established in this section except that the labeling established in § 1.17(c) of this chapter, including the order for listing vitamins and minerals established in § 1.17(c) (7) (iv) of this chapter, shall be used in lieu of the labeling established in paragraph (i) (1) of this section.

(6) Raw agricultural commodities.

(f) . . .

(3) In addition to the nutrients listed in paragraph (f) (1) of this section, other vitamins and minerals recognized as essential, or probably essential, in human nutrition in their biologically active forms are vitamin K, choline, and the minerals chlorine, chromium, fluorine, manganese, molybdenum, nickel, potassium, selenium, silicon, sodium, tin, and vanadium.

(h) . . .

(2) . . . (v) "_____ supplement" for a dietary supplement containing a single vitamin or mineral listed in paragraph (f) of this section (the blank to be filled in with the name of the vitamin or mineral).

(i) . . .

(1) Immediately following the name and group designation on the principal display panel, as required by paragraph (h) of this section, or on the information panel under § 1.8d of this chapter, if insufficient space is available on the principal display panel, the label shall bear a listing in tabular form of each of the vitamins and/or minerals supplied by the specified daily quantity of the dietary supplement, such daily quantity being specified at the top of the list. The vitamins and/or minerals shall be described by the names appearing in paragraph (f) of this section, shall appear in the order listed in paragraph (f) of this section, and shall be grouped and identified separately as "vitamins" and/or "minerals" without reference to "mandatory" or "optional." The quantity of each vitamin and/or mineral present in a specified daily quantity of the dietary supplement shall be stated as a part of this list and expressed in per-

centage of the U.S. RDA for each specific group for which the supplement is offered. The quantity of each vitamin and/or mineral present in the specified daily quantity of the dietary supplement shall also appear in the tabular listing in terms of the unit of measures specified in paragraph (f) of this section. If the dietary supplement consists of a vitamin or mineral for which no U.S. RDA has been established, the principal display panel shall state the number of milligrams or other recognized unit of measure of such nutrient supplied by the food when consumed in the specified quantity during a period of 1 day followed by the statement "No U.S. Recommended Daily Allowance (U.S. RDA) has been established for this nutrient".

(n) (1) Any food product which meets the definition of a dietary supplement in paragraph (a) of this section and which is not subject to any of the exemptions set forth in paragraph (e) of this section and which fails to comply with the requirements of this section (including a multicomponent supplement which offers an added vitamin or mineral not permitted by this section or which offers a greater potency of any vitamin or mineral than is permitted by this section) will be deemed to be in violation of section 403(g) of the act (21 U.S.C. 343(g)), which provides that a food shall be deemed to be misbranded if it purports to be or is represented as a food for which a definition and standard of identity has been prescribed, unless it conforms to the definition standard.

(2) Restrictions on the maximum potency of vitamins and minerals sold individually as dietary supplements, or other restrictions on dietary supplement use of a vitamin or mineral, may be imposed for reasons of safety by other regulations or by the act. For convenience, certain restrictions are cross-referenced below:

(i) Vitamin A. See § 250.109 of this chapter.

(ii) Vitamin D. See § 250.110 of this chapter.

(iii) Folic acid. See § 121.1134 of this chapter.

(iv) Iodine. See §§ 121.1073 and 121.1149 of this chapter.

(v) Copper. See § 121.101(d) (5) of this chapter.

(vi) Fluorine. See § 121.10 of this chapter.

(vii) Potassium. See § 201.306 of this chapter.

(viii) Any vitamin or mineral which is included in a dietary supplement and which is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown to be safe under the conditions of its intended use is a food additive within the meaning of section 201(s) of the act (21 U.S.C. 321 (s)), and pursuant to sections 402(a) (2) (C) and 409 of the act (21 U.S.C. 342(a) (2) (C) and 343) such use is illegal in the absence of a food additive regulation approving such use. A listing of some of the

vitamins, minerals, and compounds with vitamin and/or mineral properties which are generally recognized as safe, and which thus may lawfully be used without a food additive regulation, appears at § 121.101(d)(5) of this chapter.

(3) Compliance with the requirements of this section does not exempt a dietary supplement of vitamins and/or minerals from the requirements of any other applicable regulations or requirements of the act, whether or not cross-referenced herein.

PART 125—LABEL STATEMENTS CONCERNING DIETARY PROPERTIES OF FOOD PURPORTING TO BE OR REPRESENTED FOR SPECIAL DIETARY USES

2. Section 125.1 is amended by revising paragraph (c) and by revoking paragraph (h), as follows:

§ 125.1 Definitions and interpretations of terms.

(c) In addition to the nutrients listed in paragraph (b) of this section, the following other vitamins and minerals are essential or probably essential in human nutrition in their biologically active forms but no U.S. RDA's have been established for them: Vitamin K, choline, and the minerals chlorine, chromium, fluorine, manganese, molybdenum, nickel, potassium, selenium, silicon, sodium, tin, and vanadium.

(h) [Revoked]

3. Section 125.2 is amended by revising paragraph (b)(2) to read as follows:

§ 125.2 General label statements; dietary properties; value; placement.

(b) . . .

(2) That a balanced diet of ordinary foods cannot supply adequate amounts of nutrients: *Provided*, That representations may be made that it is often impractical to supply the iron requirements of infants, children, and women of child-bearing age with a diet of conventional foods.

4. Section 125.3 is amended by revising paragraph (a) and adding a new paragraph (c) as follows:

§ 125.3 Label statements relating to vitamins and minerals.

(a)(1) Vitamins and minerals for which U.S. RDA's are established. If a food purports or is represented to be for special dietary use because of vitamin or mineral properties, the label shall bear a statement of the percentage of the U.S. RDA of such vitamins and minerals, as set forth in § 125.1(b), supplied by such food when consumed in a specified quantity during a period of 1 day. The quantity specified shall be a reasonable quantity suitable for and practicable of consumption within 1 day. The order in which the nutrients appear on the label shall be in the order listed in § 125.1(b), except when other regulations indicate otherwise. Immediately preceding the declaration of vitamin and mineral content, the following heading shall be stated, "Percentage of U.S. Recommended Daily Allowances (U.S. RDA)". If such purported or represented special dietary use is for persons within one or more age groups for which the recommended daily allowance is set, such statement shall include the percentage for each age group. When such proportion or percentage is a whole number and a fraction or a whole number and a decimal, it shall be expressed as the whole number disregarding the fraction or decimal. The total quantity of vitamins or minerals in a food shall be no less than the amount declared, and no more than a reasonable amount above the declared quantity. Reasonable variations caused by heat, light, oxidation, storage, transportation, or unavoidable deviations in good manufacturing practice are recognized.

(2) Vitamins and minerals for which no U.S. RDA's are established. If a food purports or is represented to be for special dietary use because of the presence of a vitamin or mineral for which no U.S. RDA has been established, the quantity of each such nutrient (in the order listed in § 125.1(c), except when other regulations provide otherwise) supplied by the food when consumed in a specified quantity during a period of one day shall be stated on the label in milligrams or other recognized unit of measure (the quantity of consumption specified shall be a reasonable quantity suitable for and practicable of consumption within 1 day) followed by the statement "No U.S. Recommended Daily Allowance (U.S. RDA) has been established for this nutrient".

(3) Where both paragraph (a)(1) and paragraph (a)(2) of this section are applicable to a food, the information required by paragraph (a)(2) of this section shall follow immediately after the information required by paragraph (a)(1) of this section and the quantity of consumption specified pursuant to each paragraph shall be the same.

(c) Whenever a representation is included in labeling of a food for special dietary uses to the effect that vitamin and/or mineral content is derived from a particular source, the representation shall immediately be accompanied, in type of at least equal size and prominence, by a statement of the percentage of the vitamin and/or mineral content provided by that source. For example, a representation such as "contains vitamin A from alfalfa" must immediately be accompanied by a statement such as "— percent of the vitamin A content of this product is derived from alfalfa"; alternatively, a single statement incorporating the percentage declaration would be appropriate, for example, "— percent of the vitamin A provided by alfalfa".

Any interested person may, on or before July 14, 1975, file with the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852, written exceptions to these tentative amendments. Exceptions and accompanying briefs shall be submitted in quintuplicate.

The Commissioner will endeavor to issue final revised regulations, taking into consideration the relative merits of the applications for additional dietary supplement formulations, the record of the examination of Dr. Harper and the report of the Administrative Law Judge, and the exceptions received to the tentative amendments, as rapidly as is feasible. The final regulations will be published in the FEDERAL REGISTER.

Dated: May 17, 1975.

A. M. SCHMIDT,
Commissioner of Food and Drugs.
[FR Doc.75-13675 Filed 5-27-75;8:45 am]

Addendum, page 7

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER B—FOOD AND FOOD PRODUCTS

[Docket No. 75N-0107]

PART 80—DEFINITIONS AND STANDARDS OF IDENTITY FOR FOODS FOR SPECIAL DIETARY USES

PART 125—LABEL STATEMENTS CONCERNING DIETARY PROPERTIES OF FOOD PURPORTING TO BE OR REPRESENTED FOR SPECIAL DIETARY USES

Vitamin and Mineral Products

The Food and Drug Administration (FDA) is issuing final revised regulations governing the labeling and composition of dietary supplements and other foods which purport or are represented to be for special dietary use because of vitamin and/or mineral properties, in compliance with remand directions by the United States Court of Appeals for the Second Circuit, *National Nutritional Foods Assn. v. Food and Drug Administration*, 504 F.2d 761 (2d Cir. 1974), and in compliance with new amendments to the Federal Food, Drug, and Cosmetic Act concerning vitamins and minerals. Voluntary compliance with these regulations may begin October 19, 1976 and all products initially introduced into interstate commerce on or after January 1, 1978, shall fully comply.

A. HISTORY

In the FEDERAL REGISTER of August 2, 1973 (38 FR 20708, 20730), the Commissioner of Food and Drugs established new regulations to govern the labeling and composition of dietary supplements and other foods that purport or are represented to be for special dietary use because of vitamin and/or mineral properties in §§ 80.1, 125.1, 125.2, and 125.3 (21 CFR 80.1, 125.1, 125.2, 125.3). Subsequently, 15 petitions for review of these regulations were filed in various United States courts of appeals, and all petitions were eventually consolidated in the United States Court of Appeals for the Second Circuit. After extensive briefing and argument, that Court rendered judgment on August 15, 1974 (*National Nutritional Foods Association v. Food and Drug Administration*, 504 F.2d 761 (2d Cir. 1974)). While the Court stated that it was "broadly sustaining the regulations" (504 F.2d 786), it nevertheless remanded the regulations to FDA for certain further action. A copy of the Court's judgment is on file with the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852.

A petition for certiorari, asking the United States Supreme Court to review the decision by the Court of Appeals, was filed by petitioners in 2 of the 15 petitions for review which had been consolidated before the Second Circuit. On February 24, 1975, the Supreme Court denied the petition for certiorari (420 U.S. 946). Accordingly, by a document published in the FEDERAL REGISTER of May 28, 1975 (40 FR 23241), FDA began the process

of compliance with the remand directions of the Court of Appeals. Pursuant to those directions, the May 28, 1975 document addressed three separate matters:

1. *Applications for additional formulations.* The August 2, 1973 regulations established definitions and standards of identity for dietary supplements of vitamins and minerals which would have permitted five basic types of preparations (a multivitamin and multimineral supplement, a multivitamin supplement, a multimineral supplement, a multivitamin supplement with iron, and a supplement consisting of any single vitamin or mineral) and specified certain mandatory and optional vitamins and minerals for inclusion in multivitamin supplements. While the Court of Appeals upheld FDA's authority, pursuant to section 304 of the act (21 U.S.C. 341), to establish definitions and standards of identity for dietary supplements of vitamins and minerals, it directed FDA to receive and consider applications for additional formulations of dietary supplements to be permitted by the regulations. Therefore, in the May 28, 1975 document, the Commissioner invited applications from any interested persons who desired that additional formulations of dietary supplements of vitamins and/or minerals be permitted under the regulations. The applications received and the Commissioner's action thereon are discussed below in section B.

2. *Reopening of hearing.* The Court's decision also instructed FDA to reopen the administrative hearing on which the regulations were based, for the limited purpose of permitting cross-examination of one witness. Accordingly, the May 28, 1975 document gave preliminary notice of reopening of the hearing. The reopened hearing was held at FDA headquarters in Rockville, Maryland, from November 10 through 17, 1975. The report and recommended order of the Administrative Law Judge was entered on February 20, 1976. Thereafter, hearing participants filed exceptions to the report and recommended order. The reopened hearing, the report and recommended order of the Administrative Law Judge, and the Commissioner's action upon the exceptions filed by the hearing participants in response to the report and recommended order are discussed below in section C.

3. *Other amendments to the regulations pursuant to the decision by the Court of Appeals.* After careful consideration of the Court of Appeals' decision, the Commissioner concluded that a number of revisions should be made in the regulations. Accordingly, several tentative amendments to the regulations were published in the May 23, 1975 document. In the same document, the Commissioner explained his rationale for the tentative amendments and invited interested persons to file exceptions. The exceptions received and the Commissioner's action thereon are discussed below in section D.

4. *The 1976 Vitamin and Mineral Amendments to the Federal Food, Drug,*

and Cosmetic Act. While FDA was in the process of revising the vitamin/mineral regulations pursuant to the remand directions of the Court of Appeals, Congress enacted new legislation (Pub. L. 94-273, Title V, April 22, 1976) that restricts FDA's authority to limit the maximum potency of vitamins and minerals and inclusion of ingredients in dietary supplements which are offered for use by adults (other than pregnant or lactating women) and are recognized as safe. The effect of the new legislation upon FDA's regulations is discussed below in section E.

5. *Other important matters.* In section F below, the Commissioner discusses: (1) the reorganization and recodification of the regulations to improve clarity, (2) the effective date of the regulations, and (3) judicial review.

6. *Final revised regulations.* Finally, pursuant to: (1) his evaluation of the applications for additional formulations as discussed in section B below, (2) his evaluation of the reopened hearing, as discussed in section C below, (3) his evaluation of the exceptions received in response to the tentative amendments to the vitamin/mineral regulations, as discussed in section D below, (4) the requirements of the 1976 Vitamin and Mineral Amendments to the Federal Food, Drug, and Cosmetic Act, as discussed in section E below, and (5) certain other considerations, as discussed in section F below, the Commissioner issues final revised regulations under §§ 80.1, 125.1, 125.2, and 125.3.

B. APPLICATION FOR APPROVAL OF ADDITIONAL FORMULATIONS

In the May 28, 1975 document, the Commissioner invited applications from any interested persons who desired that additional formulations of dietary supplements of vitamins and/or minerals be permitted under § 80.1. The Commissioner advised that applications were invited both for additional combinations of ingredients and/or for increased potency of any vitamin(s) or mineral(s) within a combination. The Commissioner also published tentative amendments to the regulations to permit sale of a dietary supplement consisting of a single vitamin or mineral without limit on maximum potency as long as the preparation is generally recognized as safe, as discussed in section D below.

The Commissioner originally provided that such applications must be filed with FDA by July 14, 1975. However, pursuant to requests for extension of time for filing of such applications, the deadline for filing was subsequently extended until August 29, 1975 by notice published in the FEDERAL REGISTER of July 10, 1975 (40 FR 29039).

Applications were received for a total of 73 dietary supplement formulations by the close of the extended time period allotted for the filing of applications. On April 29, 1976, the FDA Bureau of Foods Assistant Associate Director for Nutrition and Consumer Sciences forwarded to the Acting Associate Director a report on the "Applications for Additional Diet-

ary Supplement Formulations." The report considered all submissions that had been received (including some submissions received after the August 29, 1975, deadline), and it recommended that eight additional formulations be authorized.

However, the recommendations contained in the report were generally rendered moot by the enactment of the 1976 Vitamin and Mineral Amendments to the Federal Food, Drug, and Cosmetic Act. The new legislation prevents FDA from limiting the inclusion of ingredients or maximum potency of vitamins and minerals in dietary supplement formulations (intended for ingestion in tablet, capsule, droplet or other form not simulating or represented as conventional food) that are offered for use by adults, other than pregnant or lactating women, and are recognized as safe. (The new legislation is discussed in detail in section E below.) The regulations are revised below to conform to the restrictions imposed upon FDA by the new legislation, i.e., the regulations no longer limit the inclusion of ingredients or maximum potency of vitamins and/or minerals in dietary supplement formulations (intended for ingestion in tablet, capsule, droplet or other form not simulating or represented as conventional food) that are represented for use by adults, other than pregnant or lactating women, and are recognized as safe. Accordingly, there is not need for the Commissioner to rule upon the merits of most of the preparations for which applications were filed because, with respect to most such preparations, the regulations no longer purport to establish a limited number of approved formulations.

However, because the Commissioner believes that the report prepared by the Assistant Associate Director for Nutrition and Consumer Sciences may be useful to the public, the Commissioner has determined to make it available. As an intra-agency memorandum making recommendations for action by the FDA, this document would not be required to be disclosed under the Freedom of Information Act. However, in the exercise of his discretion, the Commissioner has forwarded a copy of the document to the office of the Hearing Clerk, Food and Drug Administration, where it will be available for public scrutiny; copies may be requested at cost. (The report is not an official statement of FDA policy; indeed, the Commissioner might not have accepted its recommendations. Yet, as a comprehensive review of a controversial matter by informed agency staff, it should be of interest and use to the public.)

A few of the applications concerned preparations that are not automatically authorized by the new vitamin/mineral legislation. The new legislation does not apply, for example, to preparations represented for use by persons under the age of 12 years, by pregnant or lactating women, or by individuals in the treatment or management of specific diseases or disorders. The Commissioner's action on these applications is as follows:

1. *Dietary supplement of vitamins A, D, and C for infants and young children.*

Three applications were for a pediatric dietary supplement preparation containing vitamins A, D, and C. One of these applications requested inclusion of vitamin E; another requested optional inclusion of iron. The Commissioner agrees that a dietary supplement should be authorized which provides vitamins A, D, and C for infants and young children, with provision for optional inclusion of vitamin E and/or iron.

The combination of vitamins A, D, and C has been recommended for patient use by pediatricians for many years. This combination is appropriate for use as a dietary supplement in those cases when non-breast-fed infants receive unfortified fat-free milk formulas which lack sufficient quantities of these nutrients. The American Academy of Pediatrics has long recognized this kind of preparation as a desirable combination for supplementing the diets of some infants and young children.

The need for supplemental amounts of iron and vitamin E is based on a similar rationale, and pediatric practice has favored having the option of providing iron and vitamin E along with vitamins A, D, and C. Low birth weight infants, especially prematurely born infants, may be prone to develop an anemia due to inadequate stores of body iron. Similarly, stores of vitamin E at birth are commonly less for the premature than for the full-term infant, and early provision for vitamin E sufficiency in these infants is desirable to minimize the risk of hemolytic anemia. Because of these potential risks, it is appropriate to provide for the optional inclusion of vitamin E and iron in the vitamins A, D, and C supplement. The regulations have been amended below to provide for such a preparation.

2. *Dietary supplement for pregnant women (a prenatal preparation).* An application was received for a "prenatal dietary supplement" that would deviate from the present formulation authorized by § 89.1 for pregnant or lactating women only in that the range of vitamin B₁₂ would be increased from 2-4 mg to 10-40 mg. This proposed change was supported by general statements that "pregnancy results in abnormal tryptophan metabolism," and that production of tryptophan metabolites formed during this period are "normalized by high intake of vitamin B₁₂." The only evidence cited which appeared to support this assertion was a short article in *Lancet* by an investigator associated with the Indian Council of Medical Research, Hyderabad, India (Iyengar, L., "Oral Lesions in Pregnancy," *Lancet*, 1: 680-681, 1973). However, after examination of this article, it was concluded that it did not support the petitioner's hypothesis. The author of the article summarized by saying that the results of her investigation "suggest that oral lesions in pregnancy particularly common in pregnant women of low-income groups in India have a dual origin—both pyridoxine and riboflavin having aetiological roles."

The Commissioner concludes that it would be contrary to sound public health policy to authorize such a great increase

(5 to 10 times) in vitamin B₁₂ in preparations represented for use by pregnant women without more supporting data.

3. *Vitamin/mineral preparation for women taking estrogens.* Two applications were received for multivitamin supplements for women taking estrogen-containing oral contraceptives or other estrogen preparations. The Commissioner recognizes that use of estrogen preparation may affect the body's nutrient needs. However, vitamin/mineral preparations intended to meet such needs are adjuncts to prescription drug therapy, since estrogen preparations are available only on prescription. The Commissioner believes that vitamin/mineral preparations taken to meet special vitamin or mineral needs occasioned by drug therapy should be considered drugs. The Commissioner will await receipt of the recommendations of the Panel on OTC (over-the-counter) Vitamin, Mineral, and Hematinic Drug Products before making any determination about appropriate nutrient preparations for use by women taking estrogen-containing drugs. In the meantime, the Commissioner will regard safe and nutritionally rational vitamin and/or mineral preparations represented for use by women taking estrogen-containing drugs to be appropriate for sale as over-the-counter drugs, and thus not subject to the formulation restrictions imposed by the dietary supplement (special dietary food) regulations issued below.

In summary, it is unnecessary to rule on most of the applications received for additional formulations of dietary supplements because the regulations issued below have been revised to conform to the requirements of the 1976 Vitamin and Mineral Amendments to the Federal Food, Drug, and Cosmetic Act; i.e., the regulations no longer impose limits on the inclusion of ingredients or maximum potency of vitamins and minerals in most dietary supplement products that are offered for use by adults, other than pregnant or lactating women, and are recognized as safe. The regulations have, however, been amended to authorize an additional pediatric dietary supplement consisting of vitamins A, D, and C (with provision for the optional inclusion of vitamin E and/or iron) represented for use by infants and children under 4 years old.

C. REOPENED HEARING

The Court of Appeals remanded the regulations to FDA "with instructions to reopen the record for the limited purpose of permitting reasonable cross-examination of Dr. (William H.) Sebrell (or, if he is not available, some other qualified member of the [Food and Nutrition] Board [of the National Academy of Sciences]) by Dr. (Miles H.) Robinson or counsel of some other similarly interested participants" (504 F.2d at 799).

A preliminary notice of reopening of hearing was published in the May 22, 1975 document, which advised inter alia that the hearing would be reopened pursuant to the Court's direction and that Dr. Alfred E. Harper, Professor of Nutri-

tion Sciences and Biochemistry and Chairman of the Department of Nutritional Sciences, University of Wisconsin, would be made available for examination. As explained in the preliminary notice, Dr. Sebrell was no longer a member of the Food and Nutrition Board, and arrangements were made to call instead Dr. Harper, who was Dr. Sebrell's successor as the Chairman of the Committee on Dietary Allowances of the Food and Nutrition Board, serving in that capacity at the time of development and publication of the most recent recommended dietary allowances (RDA's) contained in the (eighth) edition of the National Academy of Sciences/National Research Council's "Recommended Dietary Allowances."

The Notice of Reopening of Hearing was published in the FEDERAL REGISTER of September 30, 1975 (40 FR 44357). Inter alia, the notice stated that Dr. Harper would be available to "respond to inquiry by those opposed to the regulations, concerning: (a) the methodology employed in development of the recommended dietary allowances by the Board and the scientific foundation upon which these allowances are based, (b) the scientific appropriateness of Food and Drug Administration use of the Board's recommended dietary allowances, and (c) possible biases or conflicts of interest on the part of the Board, as well as any other subjects deemed by the Administrative Law Judge to be relevant to the examination mandated by the Court of Appeals."

The presiding officer at the hearing was Administrative Law Judge Daniel J. Davidson. A prehearing conference was held by Judge Davidson on October 31, 1975, and the reopened hearing was held from November 10 through 17, 1975.

Twenty-one parties appeared at the hearing. Pursuant to the terms of the remand by the Court of Appeals, Dr. Miles H. Robinson took a leading role in the examination of Dr. Harper. However, examination was not restricted to Dr. Robinson, and several other participants also engaged in examination.

On February 20, 1976, Judge Davidson entered in the docket his report and recommended order on the reopened hearing. Judge Davidson's "ultimate findings and order" were as follows:

(1) Alleged biases and/or conflicts of interests of the witness or other members of the Food and Nutrition Board have not been established in any degree which might reasonably be interpreted as affecting the judgment of the witness or other members of the Board in determining the RDA's.

(2) Although the Board determined the RDA's as a guide to sound nutrition for a healthy population, and not as standards for regulatory purposes, there is nothing inconsistent or unsound in using the RDA's as a basis for regulatory determinations [sic] as to labeling and nutritional content requirements, and

(3) Information adduced through detailed cross-examination into the scientific basis and methodology utilized by the Board in determining the RDA's does not require adoption of regulations differing from those published.

Thereafter, exceptions to the report and recommended order were filed by hearing participants. All exceptions have been examined with care, and, as discussed in detail below, the Commissioner has concluded that the examination of Dr. Harper at the reopened hearing has given no cause for revision of the regulations; he accepts the report and recommended order by Judge Davidson without change. Thus, no revision arising out of the reopened hearing has been made in the regulations. (The regulations have, however, been revised extensively for other reasons, i.e., because of the limitations on FDA authority imposed by the 1976 Vitamin and Mineral Amendments to the Federal Food, Drug, and Cosmetic Act, as discussed in section E below, because of exceptions received in response to the tentative amendments to the regulations published May 28, 1975, as discussed in section D below, and pursuant to applications for additional formulations, as discussed in section B above.)

The transcript of the prehearing conference and of the reopened hearing, the report and recommended order of Judge Davidson, and all briefs, exhibits, exceptions, and other memoranda filed by the hearing participants are available for public inspection in the office of the Hearing Clerk, Food and Drug Administration.

After enactment of the 1976 Vitamin and Mineral Amendments to the Federal Food, Drug, and Cosmetic Act, which generally prohibit the Commissioner from imposing maximum limits on potency of a dietary supplement (discussed below, section E), the Commissioner considered whether it might no longer be necessary to rule upon the exceptions received in response to the report and recommended order of the Administrative Law Judge. In that the Court of Appeals, in remanding the regulations with directions to reopen the hearing, had stated that the remand would not have been necessary if the U.S. Recommended Daily Allowances (U.S. RDA's) had not been used to limit potency:

As earlier noted, several petitioners do not object to the basic requirement of § 125.3(a), that "the label shall bear a statement of the percentage of the U.S. RDA of such vitamins and minerals, as set forth in § 125.1(b), supplied by such food when consumed in a specific quantity during a period of 1 day." . . . In any event we see no infirmity in it. Whatever objections there may be to the U.S. RDA's when used as a basis for prohibiting the sale as dietary supplements of products exceeding the upper limits—and we have sustained these only because of the blatantly erroneous restriction on the cross-examination of Dr. Sebrell . . . they have no such force when the U.S. RDA's are used simply as measuring rods to inform the consumer what he is getting. (504 F.2d 799.)

However, since the reopened hearing had been concluded and exceptions had already been filed by the time the new legislation was enacted, the Commissioner determined that he should complete the hearing process and review the record and the exceptions received to determine whether any evidence had

been brought forth which might impugn the U.S. RDA's. Accordingly, the exceptions filed with the Commissioner in response to the report and recommended order of Administrative Law Judge Daniel J. Davidson, and the Commissioner's conclusions in response thereto, are discussed below:

1. *Allegations of bias and conflict of interest.* Dr. Miles H. Robinson, representing himself and the Federation of Homemakers, Ms. Mary S. Hill, Mr. Ralph P. Glaser, Mr. Karl F. Lutz, Ms. Jamie A. Meeter, and the National Health Federation, took exception to the Administrative Law Judge's finding that the alleged bias and/or conflict of interest of Dr. Harper or other members of the Food and Nutrition Board was not established in any degree that might reasonably be interpreted as affecting their judgment (Tr. 32530-32532, 32538, 32535-32536, 32798, 32498, 32500, 32502, 32506, 32509, 32523, 32525-32527, 32513, 32533-32534, 32589, 32719-32721, 32585, 32503-32504, 32804, 32801-32802, P-1164, P-1165, pp. 3, 16, 18, 21, 22, 75, 76). However, the examination of Dr. Harper demonstrated that this exception is without merit (Tr. 32498-32506, 32518, 32539-32532, 32533-32537, 32798-32799, 32512-32514, 32516, 32518-32519, 32523-32527, 32558, 32506-32507, 32589, 32573, 32582-32535, 32719-32722, 32726, 32999, 32930, 32932-32941, 32892, 32804-32807, 32828-32830, 32833, 32590, 32815-32818, 32821-32824). Dr. Harper testified that he did not know of any occasion when anyone on the Food and Nutrition Board had been influenced by any member of the food industry in the setting of the National Academy of Sciences National Research Council's Recommended Dietary Allowances and further explained that there were policies adopted by the Committee on Dietary Allowances (hereafter "the Committee") to ensure that its members were not influenced by the food industry (Tr. 32589, 33381-33385).

One particular allegation was that Dr. Harper was the first professor at the Massachusetts Institute of Technology (hereafter "MIT") to receive a grant from General Foods Corporation. However, the record shows no conflict of interest. The grant to MIT merely provided funds which MIT ultimately chose to use for Dr. Harper's salary, which, as a tenured professor, he would have received in

The Food and Drug Administration's regulations provide: "The U.S. Recommended Daily Allowances (U.S. RDA's) have been derived by the Food and Drug Administration from the Recommended Dietary Allowances published by the Food and Nutrition Board, National Academy of Sciences National Research Council, and are subject to amendment as more knowledge on human nutrient requirements becomes available." (See §§ 125.1(d)(2) and 125.1(b)(2) of the final revised regulations promulgated below, formerly codified in the August 2, 1973 regulations at §§ 50.1(f)(2) and 125.1(b)(1).) The National Academy of Sciences' RDA's are established by the Food and Nutrition Board of the National Academy of Sciences after recommendation of its Committee on Dietary Allowances (Tr. 33314-33317).

any event (Tr. 32523). Dr. Harper was appointed a Professor of Nutrition at MIT before MIT had received any support from General Foods (Tr. 32524), and when he left MIT in 1965, the grant continued to fund that faculty position until 1975 (Tr. 32525). Thus, Dr. Harper's connection with the grant was fortuitous, and the grant provides no sound basis for the allegations of bias and conflict of interest.

It was also alleged that in 1975 General Foods instituted an annual grant of \$50,000 to the University of Wisconsin, where Dr. Harper currently teaches, and it was implied that this was somehow connected with Dr. Harper's agreement to testify at the FDA hearing. However, Dr. Harper has no control over the research being funded by the grant (Tr. 32527). It is Dr. W. G. Hoekstra who holds the chair funded by this grant and who controls the use of the money (Tr. 32527-32528). This grant does not present a conflict of interest.

Dr. Robinson, et al., also asserted that a telegram sent to Senator William Proxmire by Dr. Harper demonstrated bias. In this telegram Dr. Harper challenged the accuracy of a speech by the Senator relating to the U.S. RDA's. The exception alleged that during cross-examination Dr. Harper retracted his views expressed in the telegram. The record indicates otherwise (Tr. 32815-32822). Indeed, when asked by Dr. Robinson, Dr. Harper gave a specific example of an inaccuracy in the Senator's speech (32823). The Commissioner concludes that Dr. Harper's telegram was motivated by concern that inaccurate statements had been made about the RDA's, and that such concern for accuracy is not a "bias" which should disqualify a witness.

The exception also alleged that Dr. Harper had consulted with the Searle Drug Company concerning the sweetening substance, Aspartame, which is not a vitamin or mineral. The record indicates that Searle is a drug and chemical manufacturer, not a food processor, and that the company has little, if any, interest in the RDA's (Tr. 32502, 32503, 32507, 32509-32513). There is no evidence of record to suggest that Searle would want to "fix" the RDA's at low levels, as the exception suggests. (As a manufacturer and supplier of food chemicals, it would seem—if interested at all—that the company, as a potential seller of vitamins and minerals, would have a bias in favor of increasing the amount of a vitamin or mineral needed to attain the RDA level.) Nevertheless, the exception maintained that General Foods and other food processors could "exert considerable influence on Dr. Harper through his Aspartame connection to get the kind of RDA's most congenial to their business operations" (Exceptions of Dr. Miles H. Robinson, et al., March 22, 1976, p. B-3). In support of this argument, the exception asserted that General Foods "put up" \$15 million toward building an Aspartame plant for Searle. The Commissioner concludes that there is no evidence on the record to support any connection between General Foods and Searle involv-

ing any significant interest in dietary allowances for vitamins and minerals, or any other evidence to support the allegations of bias and conflict of interest in this respect.

In sum, the evidence adduced does not show any financial or other interest that would warrant a finding of bias or conflict of interest affecting the judgment of those responsible for developing the RDA's.

2. *Allegations of disregard for "optimum health."* Dr. Miles H. Robinson, et al., took exception to what was characterized as Dr. Harper's "disregard for optimum health." Although the RDA's are set at a level that will be adequate for virtually all normal people in the United States, the exception suggested that the RDA's should be set at a level to provide "optimum health" to most people and that to do otherwise results in the RDA's being set at too low a level (Tr. 32582-32583, 32978, 32976, 32586, 32585). On cross-examination, Dr. Harper explained that "optimum health" is an unscientific term which cannot be defined (Tr. 32573, 32582-32583). Dr. Harper further testified that the RDA's are set at a level that should "be adequate for most, hopefully all, healthy people in the United States" and that since there is "no evidence that increased amounts above what are recommended do anything to improve health," it would be "completely unscientific to propose larger quantities of nutrients for anyone on the basis of sheer rank speculation" (Tr. 32572-32573). Thus, this exception does not demonstrate any fault in the scientific methodology used to establish the RDA's or the appropriateness of the use of the RDA's by FDA to establish U.S. RDA's.

3. *Allegations of improper reliance on the "food supply."* Dr. Miles H. Robinson, et al., took exception to what was claimed to be an improper reliance on the "food supply" as a basis for the RDA's (Tr. 32970, 13125, 3282, 33363, 33397, 32619, 32604-32608, 32525-32527, P-1165, pp. 50, 57, 59, 60, 64, 67, 70). The exception contended that "instead of exercising great care to make use of the most sensitive criteria and biochemical tests of adequate nutrition, with proper reliance on animal experiments and sound statistical analysis . . . they have in mind a ceiling for RDA's predicated on the total amount of nutrients currently being ingested, divided by the number of people eating them (Tr. 32970)" (Exceptions of Miles H. Robinson, et al., March 22, 1976, p. D-1). This exception is inaccurate and without merit.

The amount of a nutrient in the food supply is only considered where other scientific data are not sufficient. Dr. Harper testified that the average individual requirement of a given nutrient is usually based on available information from experiments on human subjects in which objective criteria indicative of the sufficiency of nutrient intake or lack thereof (e.g., night blindness) are employed and the amount of the nutrient required to meet those objective criteria

has been met during the course of the experiment (Tr. 32969). If such data are not available, information concerning the development of nutritional deficiency in a given population coupled with observations of the amounts of nutrients required to prevent, cure, or alleviate the signs or deficiency is then considered (Tr. 32969).

It is only when both of these preferred sources of information referred to in the above paragraph are insufficient, that the quantity of a nutrient provided in the food supply consumed by a particular population group is considered (Tr. 32970). Furthermore, the nutrient requirement figure derived from all considerations is not used as a ceiling for the RDA (Tr. 32969). Individual variability is taken into account. The nutrient requirement figure is adjusted upward, depending on a number of factors including the use of sound statistical analysis, to establish allowances that are ample to meet the needs of the population of the United States (Tr. 32970-32971, 32606, 32672-32674, 32801, 32981, 33071, 33078).

The procedures followed by the Committee on Dietary Allowances and the Food and Nutrition Board in establishing the RDA's were explained in great detail by Dr. Harper (Tr. 33314-33317). The Committee, which is composed of recognized experts specializing in various fields of medicine, nutrition, biochemistry, and food sciences sets RDA values at levels that are determined to be safe and suitable for the maintenance of good health (Tr. 33152). As discussed in the paragraph above, data concerning the amount of a nutrient provided by the food supply are only one of several types of information used by the panel, and this method is scientifically sound.

The exception alleged that the Committee relied improperly on the food supply in establishing RDA's for vitamin E, thiamine, vitamin B₁₂, and fatty acids. However, the record does not support this allegation. For example, with respect to vitamin E, the exception contended that the Food and Nutrition Board admitted its reliance on the food supply to establish the RDA for vitamin E in the eighth edition of "Recommended Dietary Allowances" (1974) (P-1163). The exception cited a quotation which stated that "allowances are based primarily on the *d*-alpha-tocopherol content of the diets" (Ibid. p. 57). However this quotation, which comes from a discussion of the various tocopherol compounds from which vitamin E activity in food derives, was taken out of context.

The discussion from which this quotation was taken involves the manner in which food is analyzed to determine its vitamin E content. Although there are various tocopherol compounds, because of insufficient analytical data no tocopherol compounds other than *d*-alpha-tocopherol can be considered in dietary calculations. The relative contribution of other less active tocopherol compounds to the total vitamin E activity of diets in the United States has yet to be assessed. Therefore, the discussion con-

cludes that "Until more values are available for the amounts of less active tocopherols and tocotrienols in foods and until the equivalency of these compounds to *d-alpha*-tocopherol is better established, allowances are based primarily on the *d-alpha*-tocopherol content of diets" (Ibid. p. 57).

Thus, when this quotation is read in context, it is clear that the vitamin E content in food was not the sole basis for establishing the RDA for vitamin E. The NAS/NRC publication states that the recommended allowance for vitamin E is based "partly on available experimental evidence in man (Horwitt, et al., 1963) and partly on an estimate of the amount of vitamin E considered to be available in the United States food supply (Harris and Embree, 1963)" (Ibid. p. 59).

The exception also pointed out that the RDA for vitamin E was lowered in 1974, and asserted that this was due solely to the Committee's reliance on the vitamin E content of the food supply. However, this reduction in the RDA for vitamin E was also based upon a human study done by Dr. M. K. Horwitt (Tr. 33359). This experiment showed that it was only after 4 years of an intake of 1/7 of the 1968 RDA that any sign of vitamin E deficiency could be detected in red blood cells (Tr. 33359).

The exception also alleged that the Committee ignored sensitive criteria for determining vitamin E deficiency (Tr. 33363, 33397). Although there were more sensitive criteria than were used by Dr. Horwitt in the study previously mentioned, there is no evidence that sensitive criteria were improperly ignored by the Committee in their deliberations or that these criteria should have made a significant difference in establishing the 1974 RDA.

Dr. Harper stated that there were papers referred to by the Committee which involved the hemolysis test which is a more sensitive test (Tr. 33397). In addition, some of the studies referred to in the exception were not used because they were irrelevant. Dr. Harper explained that these studies involved testing the use of large doses of vitamin E as an antioxidant to counteract some environmental effect, not as a nutrient (Tr. 33397). Accordingly, the record demonstrates that relevant sensitive criteria were considered by the Committee.

Another alleged example of improper reliance on the food supply cited in the exception was an assertion that the allowances for vitamins E, C, B₁, and thiamine for infants are all largely based on what is found in human milk (P-1165, pp. 60, 64, 67). First it should be noted that for vitamin E and thiamine the allowances are also based in part on human studies (Tr. 33352, P-1165, pp. 59, 60, 67). Second, Dr. Harper was cross-examined extensively on the infant level for vitamin E, the vitamin with which he is most familiar, and his testimony demonstrated that the scientific methodology was sound (Tr. 33350-33359). A study conducted by Dr. L. J. Filer, former Chairman of the Food and Nutrition

Board, concerning the growth rates of infants fed human milk formula supported the RDA level for vitamin E (Tr. 33354). In the Commissioner's opinion, the methodology used by the Committee in establishing the RDA's for these vitamins was sound.

It is the Commissioner's conclusion that, to the extent that the Committee has relied on the food supply to establish RDA's, it has done so in accordance with sound scientific principles.

4. *Animal data.* Dr. Miles H. Robinson, et al., asserted that the Committee depended extensively on animal data (P-1165, pp. 5, 38, 39, 41, 46, 49, 50, 56, 66, 69, 70, 71, 76, 77, 79, 80) and took exception to the Committee's rejection of what was characterized in the exception as "crucial animal data" (Tr. 32852-32853, 32873-32877, 32854-32861, 32598, 32601, 32853, 32883-32884, 32851-32852, 32864, 32885-32886, 32862, 32872, 32894, 32525-32527, 32457, 32680, 32898, 32993, 33495, 33503). Mr. Warren R. Biggs made a similar exception to the use of animal data. The Commissioner concludes that the record does not support these exceptions.

The eighth edition of "Recommended Dietary Allowances" (1974) does mention some animal studies, and it appears that animal studies were used to determine the relative effectiveness of various forms of some vitamins (Tr. 32873, 32875) and the availability of some vitamins in food (Tr. 32874). However, it does not appear that such studies were extensively relied upon. Dr. Harper explained the manner in which the Food and Nutrition Board used animal data: he testified that the Food and Nutrition Board does not start with animal values and extrapolate to human values and that it is only after human values are obtained that data derived from animal studies are occasionally used to make comparisons (Tr. 32852-32853, 32883). Furthermore, Dr. Harper testified that even if there is a discrepancy between the animal value and the human value this would not necessarily invalidate the human value (Tr. 32853). Dr. Harper also testified that no animal studies are directly used in estimating the human requirements of vitamins A, D, E, C, folic acid, thiamine, riboflavin, niacin, vitamin B₆, phosphorus, iron, magnesium, zinc, iodine, and Vitamin B₁₂ (Tr. 32872-32875).

The cross-examination of Dr. Harper demonstrated that the Committee's approach to the use and nonuse of animal data was sound (Tr. 32851-32853, 32872-32877, 32854-32864, 32598, 32601, 32883-32892, 32879-32880, 32869, 32894-32901, 33495-33503). Dr. Robinson, et al., attempted to show that the Committee had rejected "crucial" animal data that allegedly indicated that the nutrient requirements for certain animals were higher than those recommended for man in the RDA's. This exception relied on a National Academy of Sciences publication entitled "Number 10-Nutrient Requirements in Laboratory Animals" (Exh. 0-936). When asked whether he had relied upon this publication in establish-

ing the RDA's, Dr. Harper testified that he had not (Tr. 32879). Dr. Harper explained that when the Food and Nutrition Board made comparisons between human and animal studies they would rely upon materials containing original experimental data. This publication (Exh. 0-936) was simply a guide for use in feeding animals for laboratory experimentation, and it contained only a summary of experimental data available in scientific literature; it was therefore inadequate to use for comparison (Tr. 32879). Dr. Harper also testified that frequently the figures used in this publication are based upon types of diets that have maintained normal growth in animals and that there has often been no effort made to determine specific requirements (Tr. 32894). Finally, Dr. Harper testified that he did not know of any good summaries of comparative animal requirements (Tr. 32894). The Commissioner concludes that the Committee acted reasonably with respect to animal data. Accordingly, the Administrative Law Judge properly excluded this booklet (Exh. 0-936) and a chart based upon the booklet (Exh. 0-931) from evidence (Tr. 32899-32901).

The exception also claimed that the Committee refused to list RDA figures on a per kilocalorie of food basis because such listing would reveal discrepancies between the RDA's and the animal data in the National Academy of Sciences booklet (Exh. 0-936). In support of this, the exception quoted Dr. Harper as having testified that the Committee "did at one time consider including such a Table (sic) 'RDA' bulletin . . . but decided it would be ineffective (too difficult) for the dietitian using the bulletin." This is a mischaracterization of the record. Dr. Harper actually said: "We decided such a table was not a very effective way of reporting the values. We did, at one time, consider including such a table in the bulletin, as it might help dietitians . . . We thought it might help them, and as we looked at it, we found that even for them it probably wouldn't be too helpful" (Tr. 32892). Dr. Harper's actual response does not support the exception, and Dr. Robinson, et al., failed otherwise to establish the necessity or utility of listing RDA figures on a per kilocalorie of food basis.

The exception also alleged that indications from animals demonstrate that nutrient requirements in humans are higher than presently estimated by the Food and Nutrition Board. There is no evidence to support this allegation. Dr. Harper testified repeatedly that there was no evidence that indicates that there are any normal individuals whose needs are not met by the RDA's (Tr. 33000, 33031, 33033, 33051, 33059, 33127-33128). Significantly, Dr. Margaret A. Kraker, the only other licensed physician participating in the hearing, took the position that the RDA's are too high. The Commissioner concludes that there is no reason to believe that significant animal data were improperly ignored or that the RDA's should be any higher than they are.

Exception also was taken to the fact that Dr. Robinson's cross-examination with respect to the nutritional requirements of animals was terminated by the Administrative Law Judge (Tr. 32835, 32898, 32900). Notwithstanding the limited reliance of the Committee on animal data, Dr. Robinson was given wide latitude in cross-examining Dr. Harper on his use of animal data (Tr. 32850-32900). It was only after Dr. Robinson continued to ask questions concerning a booklet (Exh. 0-936), which had already been held inadmissible, that the Administrative Law Judge brought the questioning on animal data to a close (Tr. 32898-32900). The record demonstrates that Dr. Robinson was given reasonable opportunity to cross-examine Dr. Harper on this subject, and the Commissioner concludes that there is no merit to this exception.

Exception also was made to a ruling by Judge Davidson sustaining an objection to a question that asked whether estimates of biotin requirements have been made on animals (Tr. 32677). Judge Davidson properly sustained the objection to this question; even Dr. Robinson agreed at the time that the question was irrelevant (Tr. 32678). Moreover, Dr. Harper later testified that "I don't think information of that type [animal data] would be of any value whatsoever in attempting to estimate a requirement for man [as to biotin] who lives in a normal relatively non-sterile environment" (Tr. 32878-32879). Thus, the record demonstrates that the question was irrelevant.

5. *Statistical methodology used by the committee.* Dr. Miles H. Robinson, et al., took exception to the statistical methodology used by the Committee (Tr. 32608, 32610-32611, 33037, 32612-32613, 32764, 33130, 32789, 33136, 33769, 32770, 33772, 32760, 32761-32762, 33036-33037, 32970, 33040-33041, 33038, 33052, 33059, 33084-33097, 33086-33087, 33160, 33020-33133, 33031-33032, 33034-33036, 33042-33044, 33051, 33054, 33056, 33076, 33065, 33254-33255). A review of Dr. Harper's cross-examination has convinced the Commissioner that the statistical methodology used by the Committee in establishing the RDA's was scientifically sound (Tr. 32608-32613, 33037, 32612-32613, 32764, 33130-33135, 32789, 33136-33137, 32769-32772, 32760-32762, 33031-33046, 32729, 32772, 32970, 33020, 33052, 33059, 33082, 33084-33097, 33100, 33156, 33109-33111, 33117, 33029-33139, 33051, 33054, 33056, 33076, 33065, 33254-33255).

The exception alleged that the Committee arbitrarily and incorrectly assumed a 15-percent coefficient of variation. However, the record shows the 15-percent figure was not arbitrarily assumed, but was based on a wide variety of biological measurements in individual studies in which the coefficient of variation came out to be 15 percent (Tr. 32612-32613, 32672-32674). There were other appropriate references relied on in arriving at this figure (Tr. 33132-33135). Dr. Harper testified that he thought 15 percent was a reasonable figure, and that if there had been sound evidence for employing a different coefficient of variation for any nutrient, such

a figure would have been employed (Tr. 32789).

The exception attempted to show that the coefficient of variation for protein varied between 17 and 27 percent based upon a book by Dr. Henry C. Sherman published in 1941. However, Dr. Harper explained that most of the work on which the coefficient of variation for protein was based had been done after 1941 by Dr. D. Mark Hegsted and Dr. Fredrick J. Stare and their associates at Harvard, by Dr. Nevin S. Scrimshaw and his associates at MIT, and by Dr. Doris H. Calloway and her associates at Berkeley (Tr. 32772). The experiments relied on by Dr. Sherman were very early experiments in which no effort was made to determine the minimum or average requirement (Tr. 32772). While Dr. Harper stated that Dr. Sherman's statistical treatment was sound, he noted that the experiments available to Dr. Sherman were done between 1890 and 1938, that there was quite a range of intake among the different subjects, and that the experiments had been done under different conditions and in different countries (Tr. 32772).

The exception also relied on the fact that the 1968 edition of the "Recommended Dietary Allowances" cited a figure of 38 percent as the coefficient of variation for vitamin C. During cross-examination, Dr. Harper explained that more recent experiments had provided more reliable information and that therefore the coefficient of variation was changed (Tr. 33136). Thus, the exception failed to demonstrate that the 15-percent coefficient of variation used by the Committee was unreliable. The board's history of willingness to employ a greater coefficient of variation, where reasonably justified, is underscored by their action in 1968 with respect to vitamin C. There was no "arbitrary adherence" to a 15-percent coefficient of variation.

Exception was also taken to the Committee's use of the Gaussian curve of normal (bell shaped) distribution in establishing RDA's. Dr. Harper did testify that there are biological phenomena for which the Gaussian distribution does not fit very well and that if the distribution for a given nutrient were non-Gaussian, the range of people not covered would be wide. However, he never testified that such non-Gaussian distribution was applicable to RDA's. In fact, he testified that: (1) the available information tends to show a Gaussian distribution (Tr. 33045), (2) there was no evidence that anybody's needs are higher than the RDA's developed using the Gaussian distribution (Tr. 33026), (3) the Gaussian distribution is not the only criterion used (Tr. 33051), (4) there are references that support the use of the Gaussian distribution (Tr. 33038-33039), and (5) the hypothesis had been successfully tested (Tr. 33045-33046). The Commissioner concludes that the exception to the use of the Gaussian curve is not well founded.

The exception further contended that the Committee's statistical methodology

was defective in that it treated each nutrient independently rather than considering the simultaneous use of all nutrients. In support of this contention, it was claimed that Dr. Harper "agreed that as a person's needs for more than one nutrient are considered, even assuming a Gaussian distribution, the percentage of the population whose nutrient needs are not met (sic) goes up, and that this is important" (Exceptions of Miles H. Robinson, et al., March 22, 1976, P. G-5). This is a mischaracterization of the record: Dr. Harper never agreed that the situation posited was anything more than an unlikely statistical hypothetical (Tr. 33082, 33109-33111, 33117). Dr. Harper also explained that this hypothetical contained assumptions that did not apply to the establishment of the RDA's (Tr. 33084, 33093, 33101, 33102, 33108, 33109). Dr. Harper testified that "we can set up the figures in any way in a hypothetical situation to get any answer" (Tr. 33111).

Dr. Harper testified that even considering all nutrients simultaneously, putting the hypothetical in practical terms, it was quite possible that the percentage of the population whose nutrient needs are met would not change—since the food supply is more than adequate, the nutrient requirements are relatively low, and people tend to consume as much food as they need (Tr. 33103). Dr. Harper further testified that the RDA's were set to exceed people's needs and that "you may well expect half the population to eat less than the RDA and still have their needs met completely" (Tr. 33078). Finally, Dr. Harper stated that this was not even an important point to discuss with respect to the RDA's, but rather with respect to the food consumption patterns of the United States and the adequacy of the food supply (Tr. 33026). The Commissioner concludes that this exception lacks merit.

Exception also was taken to two rulings of Judge Davidson which occurred during cross-examination of Dr. Harper on the subject of statistical methodology. The Commissioner has determined that these exceptions are without merit, and that the record is clear that Judge Davidson gave Dr. D. R. Davis, the cross-examiner, great leeway and was exceedingly fair during the entire cross-examination on statistical methodology (Tr. 33031-33032, 33034-33035, 33042-33044, 33049-33051, 33053, 33054-33062, 33064-33068, 33068, 33071, 33073-33076, 33085, 33089, 33092-33094, 33101-33105, 33112-33114, 33112, 33120-33123, 33125-33127, 33128, 33131, 33133). In particular, Judge Davidson properly sustained the objection on the line of questioning Dr. Davis was pursuing concerning the Gaussian distribution in that such questioning was highly repetitive. Dr. Davis had already cross-examined Dr. Harper extensively on this point (Tr. 33029-33051). Judge Davidson explained the reason for his ruling and Dr. Davis indicated that he agreed (Tr. 33055).

Exception was also taken to Judge Davidson's ruling that certain hypothetical questions on statistical probability

posed by Dr. Davis were irrelevant (Tr. 33076). This ruling was proper since there was no foundation laid showing how the statistical hypothetical related to the establishment of the RDA's (Tr. 33073-33074). Moreover, Judge Davidson allowed Dr. Davis to continue with a different hypothetical to pursue his point (Tr. 33076-33080).

G. Particular RDA levels. Dr. Miles H. Robinson, et al., took exception to the levels set for particular RDA's. With respect to vitamin A, it was alleged that the Committee should have considered the vitamin A content of the liver as a criterion for establishing the RDA and that the RDA was lower than that in Exhibit 0-936 which lists recommendation levels for laboratory animal with animal data. First, as discussed supra, Exhibit 0-936 was properly held inadmissible and does not provide a valid basis for evaluation of the RDA's for purposes of determining their scientific validity. Second, Dr. Harper testified that to the best of his knowledge no one had ever done liver biopsies in human subjects during the development of vitamin A deficiency, and that, while he wasn't certain, he thought it was highly probable that night blindness would be one of the first discernible symptoms of vitamin A deficiency. This was the criterion which the Committee used (Tr. 33426-33427), and it appears appropriate and adequate.

Moreover, when the Food and Nutrition Board and the Committee on Recommended Dietary Allowances established the RDA for vitamin A, they were fully aware that the liver was the center for the storage of vitamin A and that ingestion of excessive amounts of vitamin A results in very large accumulations of vitamin A in the liver, which can cause toxicity (Tr. 33430). Therefore, the relationship between vitamin A and the liver was considered in establishing this RDA.

The exception also noted that Dr. Harper agreed that the rat needs 19 times more vitamin A than normal during pregnancy while the human needs only 3 times more, according to the established RDA. However, Dr. Harper explained this difference. He testified that the rat produces a litter of 12 and can produce a litter every 21 days, so the proportion of the rat's body weight that may be involved in maximum reproduction is about $\frac{1}{3}$ every 23 to 35 days, whereas, a woman would use $\frac{1}{8}$ to $\frac{1}{9}$ of her body weight every 9 months (Tr. 33437-33438). This accounts for the difference which the exception incorrectly relied upon as evidence of a need for a higher RDA for vitamin A.

Exception also was taken to the fact that the Committee made no distinction between the two common forms of vitamin D, (D₂ and D₃) and alleged that the synthetic form, D₂, was less effective. Dr. Robinson relied on Exhibit 0-936 in support of what he claimed to be the lack of effectiveness of vitamin D₂. However, Dr. Harper explained that the study Dr. Robinson was referring to did not involve vitamin D deficiency, but rather

the cure of bone disease with the use of vitamin D₂ and vitamin D₃ (Tr. 33467). Furthermore, this study indicated that the Rhesus monkey, which is the one most widely used in nutritional studies, responds equally well to both forms, and that it was only some species of the South American monkey which showed a difference (Tr. 33467-33468). Dr. Harper testified that, based solely upon a study of treatment of bone disease in monkeys, it would be difficult to draw a conclusion applicable to humans (Tr. 33469).

The Committee spent a considerable amount of time deliberating on the relative effectiveness of vitamins D₂ and D₃ (Tr. 33472). Dr. Harper personally visited Dr. Roslyn Alfin-Slater and one of her students in California, as well as other people, concerning this problem (Tr. 33472). Dr. Harper testified that he had found no evidence to suggest that vitamin D₂ should be designated as the exclusive source of vitamin D for human supplementation (Tr. 33472).

With respect to vitamin E, Dr. Robinson, et al., and Mr. Warren R. Biggs objected to the lowering of the RDA from 30 IU (international units) to 15 IU in 1974 and to the criteria used in establishing the RDA. As discussed in section C.3. above, the Commissioner has concluded that the basis for establishing the RDA for vitamin E was scientifically sound.

Dr. Robinson, et al., took exception to the ruling of Judge Davidson which ended a line of questioning relating to vitamin C (Tr. 33409-33413). However, this line of questioning specifically dealt with the reduction in the RDA for vitamin C in 1974, as compared with 1968. The difference between the 1968 RDA's and the 1974 RDA's was ruled irrelevant. Since the U.S. RDA's were based on the 1968 RDA's, any subsequent revision in the NAS/NRC RDA's was beyond the scope of the hearing, which was held to inquire into the process employed in establishing the NAS/NRC RDA's to determine whether it was appropriate for FDA to use the NAS/NRC figures as a basis for the U.S. RDA's (Tr. 33409-33413). Thus, the Administrative Law Judge properly excluded all questioning concerning the difference between the 1968 and the 1974 RDA's, as discussed more fully in section C.11. below. Should any change in the U.S. RDA's be proposed in the future, all interested persons will have an opportunity to comment and otherwise participate in the rule making.

7. Allegations of prejudice and malice on the part of the Administrative Law Judge. Dr. Miles H. Robinson, et al., claimed that the Administrative Law Judge was prejudiced and that he acted with malice in presiding over the hearing (Tr. 32582, 33095, 32655, 32533, 32560, 32598, 32591, 32856-32859, 32853, 32555, 32265, 32296, 33095-33096, 33346-33347, 32556, 32533, 33093, 33112, 32904, 33092, 32553; Pretrial Hearing Tr. 17, 22, 27, 19-25, 42, 46, 70-73, 80, 102). Mr. Warren R. Biggs made a similar claim.

The record demonstrates that these allegations are without merit. Judge Da-

vidson was fair to all participants, including Dr. Robinson. At the outset, Judge Davidson stated that he would hold attorneys to a higher standard than non-attorneys which was to Dr. Robinson's benefit because he is not an attorney (Pretrial Hearing Tr. 12). Following this statement, throughout the proceedings Judge Davidson was exceedingly fair to Dr. Robinson in giving him leeway to ask questions which either bordered on being or were in fact objectionable. Judge Davidson also explained his rulings whenever Dr. Robinson became confused and even gave guidance to Dr. Robinson, who was generally unfamiliar with the rules of evidence and proper cross-examination (Tr. 32444, 32463, 32478-32481, 32484-32485, 32487, 32493, 32501, 32504-32506, 32509, 32516, 32526-32529, 32523, 32542-32546, 32555-32557, 32559-32563, 32580-32582, 32593-32601, 32603, 32736, 32834, 32654-32666, 32695-32697, 32849-32913, 33029, 33054, 33058, 33091-33095, 33112-33114, 33255, 33265, 33340-33342, 33345-33348; Pretrial Hearing Tr. 12, 17, 42, 46, 80, 102).

The record is replete with examples of Judge Davidson's attempts to be fair: Dr. Robinson asked and received advice on the proper technique for making a motion (Tr. 32499); Judge Davidson encouraged Dr. Robinson not to give up so quickly on a line of questioning to which an objection had been raised (Tr. 32501); Judge Davidson patiently explained the proper way to use exhibits (Tr. 32503-32509); Judge Davidson allowed Dr. Robinson a recess when he became confused and asked for time to consult with a lawyer (Tr. 32530-32531); and Judge Davidson even allowed Dr. Robinson to introduce an exhibit without first providing copies to other parties and counsel for FDA as required by the rules (Tr. 32590).

Finally, even Dr. Robinson commented on Judge Davidson's fairness during the hearing. In introducing Dr. Davis, who had no prior experience in cross-examination but was about to cross-examine Dr. Harper, Dr. Robinson commented "I am confident that under Your Honor's impartiality and fair guidance that all will be well" (Tr. 33029). Subsequently, Dr. Robinson again commented on how fairly Judge Davidson had conducted the hearing, noting: "I feel you are absolutely fair if you insist that the cross-examination be relevant and material and not repetitive. Personally, I am very satisfied that we are getting down to what Judge Friendly wanted . . ." (Tr. 33362). In light of these comments, and the record as a whole, contentions that Judge Davidson was prejudiced or acted with malice are without merit.

Dr. Robinson, et al., also filed the following related motions subsequent to the close of the reopened hearing:

(1) On December 12, 1975, a motion which requested that the Administrative Law Judge authorize an interlocutory appeal to the Commissioner of Judge Davidson's ruling denying leave to produce rebuttal witnesses thereafter referred to as "December 12, 1975 Motion Requesting

Interlocutory Appeal to the Commissioner");

(2) On February 6, 1976, a motion requesting Judge Davidson to rule on the December 12, 1975 Motion Requesting Interlocutory Appeal to the Commissioner (hereafter referred to as "February 6, 1976 Motion Requesting Ruling"); and

(3) On March 17, 1976, a motion requesting the Administrative Law Judge to disqualify himself (hereafter referred to as "March 17, 1976 Motion to Disqualify"). The March 17, 1976 Motion to Disqualify took issue with the conduct of Judge Davidson in refusing to consider the December 12, 1975 Motion Requesting Interlocutory Appeal to the Commissioner.

In an order dated February 9, 1976, Judge Davidson denied the February 6, 1976 Motion Requesting Ruling, and at the same time Judge Davidson further ruled that the December 12, 1975 Motion Requesting Interlocutory Appeal to the Commissioner was out of order because the hearing had been concluded on November 17, 1975, and § 2.89 (21 CFR 2.89) contemplates authorization by the Administrative Law Judge of interlocutory appeals to the Commissioner only during the pendency of a hearing and only under certain circumstances.

In the March 17, 1976 Motion to Disqualify, Dr. Robinson, et al., objected to the fact that information concerning the December 12, 1975 Motion Requesting Interlocutory Appeal to the Commissioner had to be obtained from a member of FDA's Office of General Counsel who had spoken to Judge Davidson: Dr. Robinson's wife had called FDA's Office of General Counsel on January 22, 1976; she was informed that Judge Davidson did not believe the December 12, 1975 Motion Requesting Interlocutory Appeal to the Commissioner was properly before him and that he did not intend to rule on the motion. Mrs. Robinson was advised that the matter could be pursued by making a motion to the Administrative Law Judge or by making a request directly to the Commissioner to reopen the hearing. Dr. Robinson, et al., subsequently filed the February 6, 1976 Motion Requesting Ruling which precipitated Judge Davidson's order of February 9, 1976 which denied that motion. (Dr. Robinson, et al., thereafter sent to the Commissioner a letter dated February 17, 1976, making a request to introduce rebuttal evidence; this letter and thus the merits of reopening the hearing for rebuttal testimony are ruled upon below in section C.8).

It is not improper for a member of the General Counsel's Office, who is called concerning a procedural matter that does not involve substantive issues under consideration before the Administrative Law Judge, to speak to the Judge and then relay the information received to the interested party. In fact, the Office of General Counsel was helpful to Dr. Robinson. Dr. Robinson relied on the information he received in filing a motion and sending a letter to the Commissioner, and he has made no complaints

concerning the accuracy of the procedural advice he received. (The member of the General Counsel's Office made memoranda of his conversation with Dr. Robinson and with the Administrative Law Judge—both of which were provided to Dr. Robinson and made available to the public.)

The Commissioner concludes that the Administrative Law Judge acted properly in his decision with respect to the December 12, 1975 and February 6, 1976 Motions. The March 17, 1976 Motion to Disqualify is hereby denied.

8. *Rebuttal.* Dr. Miles H. Robinson, et al., took exception to the fact that Dr. Robinson was not allowed to introduce any rebuttal testimony with respect to statistical methodology, use of animal data, and alleged defects for certain RDA's (Tr. 33495-33503, Pretrial Hearing Tr. 62-64, 72, 88-88, 96, 103-104). From the outset, Judge Davidson made it clear that pursuant to the remand directions by the Court of Appeals, the remand was for the limited purpose of reasonable cross-examination of the witness and that rebuttal would not be allowed unless foundation for impeachment of the witness was shown, i.e., there was no automatic right for those opposed to the regulations to offer rebuttal testimony or for the Government to engage in redirect examination (Pretrial Hearing Tr. 63, 64). The Court of Appeals remanded this case to FDA "with instructions to reopen the record for the limited purpose of permitting reasonable cross-examination of" one witness (504 F. 2d 799) and Judge Davidson's ruling was consistent with this.

At the close of the hearing, Dr. Robinson was given every opportunity to explain fully the reasons he had for seeking rebuttal (Tr. 33495-33500). In the Commissioner's opinion, Judge Davidson properly ruled that there was not a sufficient showing that such rebuttal evidence was necessary, especially considering that Dr. Robinson had had opportunity to introduce such evidence when he presented his case at the prior hearing.

The extensive cross-examination of Dr. Harper was sufficient for the purposes of the remand—especially since, pursuant to the 1976 Vitamin and Mineral Amendments to the Federal Food, Drug, and Cosmetic Act, the U.S. RDA's are no longer used to restrict the maximum potency of vitamins and minerals in most dietary supplements for adults. (See the quotation from the Court of Appeals, 504 F. 2d 799, discussed at the beginning of section C.) The cross-examination of the witness extended to 5 days. Having carefully considered the transcript of the reopened hearing, the Commissioner concludes that no rebuttal was needed nor was it required by the decision of the Court of Appeals.

9. *"Motion to Receive in Evidence U.S.D.A. Article on Nutrient Availability."* On March 20, 1976, after the hearing was completed, Dr. Miles H. Robinson, et al., filed with the Commissioner a "Motion to Receive in Evidence U.S.D.A. Article on Nutrient Availability." This

article was never mentioned during the reopened hearing. This article should have been produced at the hearing so that a proper foundation could have been made as to its authenticity, reliability, and relevancy. Accordingly, this motion is denied.

10. *Allegations that existing knowledge upon which RDA's are based precludes scientific reliability of the RDA's.* Dr. Margaret A. Krikker took exception to the Administrative Law Judge's finding that there was a sound scientific basis for the RDA's and asks that his finding be revised to state that the methodology employed by the Board can only be considered value judgments and that the limited existing knowledge on which such judgments are based precludes scientific reliability of the RDA's (Tr. 32971, 32983, 32910-32911, 32997, 33003, 33241, 33170, 33195-33198, 33174-33176, 32991, 33152, 33183, 33172, 33187, 33191-33192, 33237, 33222, 33223, 33178, 33209, 33261, 33266, 33163, 32993, 33239, 32992-32993, Proposed Findings 1-8 and 32 contained in Dr. Krikker's exceptions dated March 20, 1976). While it is true that the establishment of the RDA's involved a measure of judgment and that there may be some difference of opinion as to the levels set, it does not follow, nor does the record support Dr. Krikker's assertions that the established RDA's are based upon insufficient data or are otherwise scientifically unreliable (Tr. 32996, 33201, 33071, 32978, 33030, 33031, 33033, 33051, 33099, 33127, 33128, 33314-33317, 33152, 33127, 32970, 33184, 33176, 33177, 33237, 33222, 33163, 33176, 32971, 32968, 32910-32911, 32977, 33003, 33241, 33170, 33195-33198, 33174-33176, 32991, 33152, 33183, 33172, 33187, 33191-33192, 33237, 33222-33223, 33178, 33209).

In support of her exception, Dr. Krikker alleged that the ideal method for determining RDA's was not always followed and also that RDA's have not been established for about two thirds of the essential nutrients. However, Dr. Harper testified in great detail as to the procedures that were followed in establishing the RDA's (Tr. 33314-33317), and his testimony shows that the result is the best available scientific determination of the amounts of various nutrients required to maintain a healthy population (Tr. 33127, 32670, 32606, 32801, 32981, 33071, 33078).

Dr. Krikker took exception to the RDA for iron, claiming that it is too high (Proposed Findings 9-22, 27). She relied on a report of the experts of the Joint FAO/WHO (Food Agricultural Organization/World Health Organization) expert Group on Requirements of Iron, which lists 5 mg (milligrams) as the allowance for iron (both the NAS/NRC RDA and the U.S. RDA have been set at 18 mg) and she also questioned the rate of absorption for iron (10 percent) used by the Committee. Finally, she noted that the 1974 RDA for iron was increased 50 percent over the 1968 RDA. Dr. Harper indicated that he shared Dr. Krikker's concern with respect to the possible danger of excessive amounts of iron, but stated that the tolerance for iron is in

the range of 25 to 50 mg per day, and that the rate of absorption tends to go down as the amount consumed increases (Tr. 33184-33185).

Dr. Harper also agreed with Dr. Krikker that animal protein frequently carries iron that is more readily available than some of the iron from plant products (Tr. 33176). However, Dr. Harper explained that this would not necessarily increase the absorption rate since there are interactions that could reduce the availability of iron from other sources. It was on the basis of these factors that a figure of 10 percent for the absorption rate of iron was considered to be safe and proper (Tr. 33177). Finally, there is still extensive evidence of anemia (hemoglobin level lower than the standard for adequate health) in the United States. This is a major public health problem. Given this incidence of anemia, the Committee concluded that iron availability could not have been much higher than the absorption figure that they employed (Tr. 33177). The concern over anemia also resulted in the 50 percent increase in the RDA over a 10-year period (Tr. 33183). Thus, there is substantial evidence that the RDA for iron was set at a safe and appropriate level.

Dr. Krikker also raised questions with respect to whether the RDA for calcium is too high with respect to the nature of its relation to the intake of protein (Tr. 33237, Proposed Finding 23, 24). Dr. Harper explained that the reason the RDA for calcium was not lowered was because there is some indication of an imbalance that might arise from a high intake of protein, resulting in an increased loss of calcium, reflected by increased excretion in the urine (Tr. 33237). Therefore, the Committee decided not to lower the RDA for calcium until they can be certain that the calcium requirement of the American population is not being increased by the relatively high protein intake in the United States (Tr. 33237).

Dr. Krikker also expressed concern over the long-term effects of certain vitamins and minerals and the lack of adequate toxicological studies on long-term toxicity. The Commissioner shares this concern and agrees that more research is needed. In those cases where evidence indicated that high levels of exposure are not safe, he will take appropriate action. For example, the Commissioner has already promulgated regulations under §§ 250.109, 250.110, and 250.113 (21 CFR 250.109, 250.110, and 250.113) limiting, for reasons of safety, the amounts of vitamins A and D and folic acid which may be included in a preparation. The Commissioner recognizes that more research is necessary, and additional regulations will be promulgated as more information becomes available. (See also § 201.14 of the revised final regulations below, which incorporates certain safety-related restrictions upon use of vitamins and minerals.)

Dr. Krikker also proposed a number of findings based on questions she asked during her cross-examination and on

the eighth edition of the "Recommended Dietary Allowances" (1974) (Proposed Findings 25, 26, 28, 29, 31, 33, 37). However, these proposed findings were never related to the establishment of the RDA's during cross-examination of Dr. Harper. Therefore, there is no evidence on record as to what, if any, effect these matters might have on the scientific reliability of the RDA's. For example, Dr. Harper did agree that there is a difference in absorption and bioavailability of a nutrient depending upon its biological form, which varies with nutrients (Tr. 33222). Nevertheless, it was never established what effect, if any, this may have on the development or reliability of the RDA's. This is also true with respect to Dr. Krikker's proposed findings that excessive folic acid in foods may mask vitamin B₁₂ deficiency and that there is no "single minimum dietary requirement" or "single maximum safe intake" of a trace element.

Judge Davidson pointed out to Dr. Krikker this problem (of her asking questions that had no apparent relevance to the matter at hand) during her questioning with respect to iron: "Maybe I could help you if you would just put forth on the record what it is you are driving at." (Tr. 33169). Following this comment Judge Davidson helped Dr. Krikker relate her question concerning iron to the establishment of the RDA for iron by asking Dr. Harper if his impression of the RDA's "is affected by the subject matter that Dr. Krikker is trying to get into, the type of protein source, and if so, to what extent and how it entered into the deliberations of the Committee?" (Tr. 33176). While the connection between this area of inquiry and the Committee's deliberations over the RDA for iron was thereby established, a similar connection was not successfully established for the other areas of inquiry noted above. Nevertheless, the Commissioner has considered these points, and concludes that there is no evidence to support a conclusion that these factors raise a substantial question with respect to the scientific reliability of the RDA's.

11. 1974 revisions of NAS/NRC RDA's. Miles Laboratories filed an exception which asserts that the U.S. RDA's, which were developed in reliance on the 1968 NAS/NRC RDA's, should be revised pursuant to 1974 revisions of the NAS/NRC RDA's.

The Administrative Law Judge properly ruled that this matter was beyond the scope of the hearing, which was held to inquire into the process employed by the Food and Nutrition Board's Committee on Dietary Allowances in establishing the NAS/NRC RDA's to determine whether it was appropriate for FDA to use NAS/NRC figures as a basis for regulation. Moreover, the Commissioner has already stated in the May 23, 1975 document (40 FR 23243) that the changes made in the 1974 NAS/NRC RDA's are not of sufficient magnitude as they relate to overall public health to warrant similar changes in the U.S. RDA's at this time, but that it is reasonable to anticipate changes in the existing U.S. RDA's to reflect changes in the NAS/NRC

RDA's when the latter are next published.

The Commissioner has nevertheless reconsidered this issue. A review of the changes in the NAS/NRC RDA's indicates that they include a reduction (to 10) in the total number of age groupings for which values are given, reductions in the highest RDA values for each of six nutrients in each age grouping, a small increase in the value for riboflavin, and establishment of RDA's for zinc. The Commissioner notes that U.S. RDA's already exist for zinc and that they are consistent with NAS/NRC RDA's. He remains of the view that the changes in the 1974 NAS/NRC RDA's are not of sufficient magnitude to warrant changing the U.S. RDA's at this time.

The Administrative Law Judge also observed that this proceeding has been pending for 14 years and that the institution of further refinements in the U.S. RDA's at this time would only involve a needless further delay in development of final regulations (Report and Recommended Order on Limited Further Hearing, p. 10). The Commissioner agrees that the better course to follow is to establish the appropriateness and legality of the regulations at this time and make further modifications in the future when the need arises.

12. Allegations that Dr. Sebrell should have been produced as a witness. National Nutritional Foods Association, National Association of Pharmaceutical Manufacturers, and Solgar Co., Inc., took exception to the fact that Dr. Sebrell was not produced for cross-examination.

The Commissioner concludes that this exception is without merit. The Court of Appeals remanded this case "for the limited purpose of permitting reasonable cross-examination of Dr. Sebrell (or, if he is not available, some other qualified member of the Board) by Dr. Robinson or counsel for some other similarly interested participants" (504 F.2d 700). While the Commissioner was under no obligation to do so, he opened the hearing to all interested persons, and it is a group of these parties (not Dr. Robinson) which is now raising the exception to the witness produced by the agency. Dr. Robinson, who was primarily responsible for this remand, concurred in the calling of Dr. Harper in substitution for Dr. Sebrell and supported the Government opposition to the motion which sought to prevent Dr. Harper from testifying (Tr. 32443).

The record shows that Dr. Sebrell was not interested in testifying (Exhibit F-1162), and FDA has no subpoena power to require his appearance. Moreover, Dr. Harper was eminently qualified. Dr. Harper is a professor of nutrition science and biochemistry and Chairman of the Department of Nutritional Sciences, University of Wisconsin. He is widely regarded as an expert in the field of human nutrition (Govt. Exhibit P-1162, P-1163, Tr. 32435). Dr. Harper was chairman of the Committee that was responsible for the 1974 RDA's and was a member of Dr. Sebrell's committee that formulated the 1968 RDA's (Tr. 32453). Dr. Hopper also

indicated that he was in virtually complete agreement with Dr. Sebrell's testimony (Tr. 32465-32467).

During the course of the hearing, Dr. Harper was cross-examined on a wide variety of nutrients and gave an in-depth explanation of how the Committee on Dietary Allowances and the Food and Nutrition Board functioned, of how individual RDA's were established, and of the scientific basis for the work done by the Committee. While there were some exceptions filed in which parties complained that they were unable to ask Dr. Harper enough questions, no one has complained that they were unable to obtain the information they were seeking on cross-examination due to Dr. Harper's lack of knowledge on any particular subject. Dr. Harper responded to questions of seven different examiners for 5 full days on the issues set for the hearing. All opponents of the regulations were offered a full and fair opportunity to cross-examine Dr. Harper, and this cross-examination fully complied with the remand directions by the Court of Appeals.

13. Allegations concerning therapeutic usage of vitamins and minerals. Mr. Warren R. Biggs, Dr. Margaret A. Krikker, National Nutritional Foods Association, National Association of Pharmaceutical Manufacturers and Solgar Co., Inc., observed that the RDA's were not designed to cover "therapeutic" needs, noting that there are medical conditions that require special dietary treatment. These parties also state that therapeutic usage of vitamins and minerals should be treated separately and one party suggests that regulations should be promulgated to govern the use of vitamins and minerals to treat diseases.

The Commissioner advises that the definition and standard of identity for dietary supplements of vitamins and minerals, § 80.1, applies to preparations offered simply as dietary supplements of vitamins and/or minerals, not to preparations offered for use in the treatment of disease. (See § 80.1(a) (1) and (2) (iv).) With respect to vitamin-mineral preparations represented for use under medical supervision in the dietary management of specific diseases and disorders, the Commissioner concludes that applicable labeling requirements of Part 125 are appropriate.

14. Allegations that RDA's are designed primarily for dealing with population groups. Dr. Margaret A. Krikker, National Nutritional Foods Association, National Association of Pharmaceutical Manufacturers and Solgar Co., Inc., based an exception on allegations that the RDA's are designed primarily for dealing with population groups and not individuals (Tr. 32981, 32996, P-1165, p. 3). On cross-examination, Dr. Harper testified that although the RDA's are designed primarily for addressing the dietary needs of population groups, they exceed the needs of most of the population (Tr. 32931). In fact, Dr. Harper testified that it should be possible for some people to eat diets that provide less than half of the recommended dietary allowances and still meet their require-

ments regularly (Tr. 32931). The Commissioner concludes that this factor does not demonstrate that the RDA's are unreliable or inappropriate for use in establishing U.S. RDA's.

15. Exceptions to use of RDA's to limit ingredients and restrict dosage levels of nutrients. National Nutritional Foods Association, National Association of Pharmaceutical Manufacturers and Solgar Co., Inc., except to use of RDA's to place a limitation on ingredients or to restrict dosage levels of nutrients. Those objecting seem to have been concerned with "freedom of choice" by adults (Exceptions of National Nutritional Foods Association, National Association of Pharmaceutical Manufacturers and Solgar Co., Inc., p. 19). However, pursuant to the 1976 Vitamin and Mineral Amendments to the Federal Food, Drug, and Cosmetic Act (see discussion below in section E), the regulations issued below have been revised so that the RDA's are generally no longer being used to place any maximum limitation on the quantity of a nutrient or on the inclusion of a nutrient in a dietary supplement offered for use by adults, other than pregnant or lactating women. Accordingly, these exceptions are essentially moot. The Commissioner concludes that the use of RDA's to determine the potency of dietary supplements represented for use by infants, children, or pregnant or lactating women is appropriate.

16. Allegations that the Committee did not envision use of the RDA's in the manner employed by the regulations. Exceptions by Hoffman-LaRoche, Dr. Margaret A. Krikker, National Nutritional Foods Association, National Association of Pharmaceutical Manufacturers, Solgar Co., Inc., and Mr. Warren R. Biggs allege that at the time the 1968 RDA's were being developed the Committee did not envision that the FDA would use the RDA's to establish labeling and Compositional requirements (Tr. 32713, 32714, 32944, 32663-32666, 32746-32747, 32741, 32456, 32679, P-1165, pp. 13, 20). Even if, arguendo, the Committee did not have regulatory use in mind, it does not follow that the RDA's are not appropriate for use by FDA for regulatory purposes. In fact, Dr. Harper testified that he thought the RDA's were appropriate for use by FDA in developing labeling regulations and in the regulation of the nutritional value of food products (Tr. 32663-32665, 32711, 32820-32821, 33005, 33013-33014, 33208). He specifically stated that the RDA's "did provide a suitable nutritional yardstick for FDA to rely on in developing regulations" (Tr. 32944).

Moreover, the 1976 Vitamin and Mineral Amendments to the Federal Food, Drug, and Cosmetic Act provide that FDA may not rely on its authority to establish standards of identity for foods or its authority to prevent misbranding of foods to establish maximum limits on the potency of any vitamin or mineral or otherwise to restrict the combination or number of any vitamin, mineral or other ingredient in a preparation to which the legislation applies (see discussion in section E below). Thus, the regu-

lations issued below have been revised so that vitamins and minerals for adults, other than pregnant or lactating women, may be sold in any combination or potency that is generally recognized as safe and exceptions relating to this issue are essentially moot in light of this action.

The Commissioner concludes that the uses to which the RDA's were put by the FDA in developing regulations concerning dietary supplements of vitamins and minerals are scientifically appropriate. The RDA's provide a sound, scientific basis from which to draw values for regulations designed to fully inform purchasers of the special dietary value of foods and for establishing definitions and standards of identity.

17. Allegations of improper limitation on the scope of the reopened hearing. National Nutritional Foods Association, National Association of Pharmaceutical Manufacturers and Solgar Co., Inc., took exception to what they claimed were improper limitations on the scope of the reopened hearing. They contended that a hearing should have been held on the following matters: (1) limitations on potency of multi-vitamin-mineral products, (2) failure to include in multi-nutrient supplements vitamins and minerals for which there is no U.S. RDA, (3) additional formulations, and (4) the proposed requirement of setting forth in the labeling of a dietary supplement the percentages of a nutrient derived from particular sources.

These parties have misconstrued the order of the Court of Appeals. The Court of Appeals ordered the reopening of the hearing only "for the limited purpose of permitting reasonable cross-examination" of one witness and not to consider other matters such as those listed above (504 F.2d 739). The other matters are discussed under other sections of this document.

18. Certain other exceptions. Mr. Warren R. Biggs was not present during the pretrial conference or during any of the cross-examination of Dr. Harper, but he did file exceptions. These exceptions did not include any citations to the transcript. This makes these exceptions difficult to consider. Nevertheless, the Commissioner has read and considered all of the exceptions filed and responds to the extent possible under these circumstances:

Mr. Biggs alleged that there are no clinical studies to determine the validity of the RDA figures, and he claimed that the nutritional requirements were frequently set at the point of appearance of obvious gross symptoms of deficiency. First, nutrient requirements were not set at the level of obvious gross symptoms of deficiency (P-1165, p. 3). Second, the RDA's are based on human studies wherever such studies exist, or on examination of population surveys as well as consideration of the amount of a nutrient in the food supply (Tr. 32969-32971, P-1165, pp. 5-9). Thus, clinical studies were utilized, and when they were unavailable other reliable scientific criteria were used (see discussion above in section C.3).

Mr. Biggs noted that the need for thiamine increases with physical exercise. However, the Committee also recognized this factor, and took it into consideration in establishing the RDA for thiamine (*Ibid.*, p. 5).

Mr. Biggs contended that older persons generally have less of a particular vitamin or mineral in their bodies than younger persons. This is not generally so. The Committee specifically states that there is little evidence that requirements for specific essential nutrients change with advancing age (P-1165, p. 11).

Mr. Biggs also noted that there are different nutrient needs depending on age, sex and weight and also that two similar individuals can have different requirements. All of these factors were recognized by the Committee and considered in establishing the RDA's (P-1165, p. 4). Moreover, in the development of the U.S. RDA's from the RDA's, the highest RDA values from among the numerous age and sex groups reflected in the RDA's generally were selected to ensure U.S. RDA values equal to or greater than the individual RDA's from which they were derived.

Mr. Biggs also made an exception based on allegations that a person can consume the RDA of a nutrient and still have a deficiency. In this regard, Dr. Harper testified that the RDA's are the best possible guide we have to provide for adequate intake of essential nutrients under the wide variety of conditions in this country for essentially all of the normal healthy persons in the United States (Tr. 32669). Moreover, the RDA level is high enough that even if a person habitually consumes less than the recommended amounts of some nutrients, his diet is not necessarily inadequate (P-1165, p. 12).

Mr. Biggs also contends that high levels of consumption of a nutrient are frequently beneficial in curing diseases. However, there is no evidence on the record to support this contention.

The Committee stated that they are aware of no convincing evidence of unique health benefits accruing from consumption of a large excess of a nutrient (P-1165, p. 3).

Mr. Biggs also raised other exceptions which do not appear to be addressed in the record and do not appear to have been raised with Dr. Harper (Exception Nos. 1, 10, 14, 15, 16, 17, 18, 20, 21, 22, 23, 24, 25, 29, 30, 31, 33, 37, 38, 40, 41, 44, 45). The Commissioner has considered all of these to the extent possible, and he has concluded that no substantial basis for change in the regulations has been shown.

D. EXCEPTIONS TO THE MAY 28, 1975 TENTATIVE AMENDMENTS TO THE REGULATIONS

In the May 28, 1975 document, the Commissioner published several tentative amendments to §§ 80.1 and 125.1 through 125.3. Interested persons were invited to file exceptions on or before July 14, 1975.

Sixty-two exceptions were received between June 20 and October 2, 1975.

Although no extension in time for the filing of exceptions was provided, those exceptions received after July 14, 1975 have been fully considered. The exceptions received and the Commissioner's responses are as follows:

1. Numerous exceptions contended that the Commissioner was attempting to restrict the sale of vitamins and minerals unnecessarily, or, some contended, unlawfully, in particular by limiting the inclusion of ingredients or maximum potency of vitamins and minerals in dietary supplements. On the other hand, some exceptions supported the proposed regulations as drafted.

The Commissioner notes that these exceptions were written before enactment on April 22, 1976 of the vitamin and mineral amendments to the act. These amendments are discussed in detail below in section E of this preamble. The amendments prohibit FDA from limiting the inclusion of ingredients and maximum potency of vitamins and minerals in dietary supplements (intended for ingestion in tablet, capsule, droplet or other form not simulating or represented as conventional food) that are offered for use by adults other than pregnant or lactating women and are recognized as safe. The final regulations issued below have been revised to comply with these amendments to the act, thus rendering these exceptions moot.

This new legislation does not restrict FDA authority to limit the composition of dietary supplements for reasons of safety. If use of a vitamin or mineral is not generally recognized as safe, it may be used only in a manner consistent with an approving food additive regulation. For example, for reasons of safety, a food additive regulation, § 121.1134 (21 CFR 121.1134), limits the maximum potency of the vitamin folic acid, which may be used in dietary supplements; and Congress, in passing the 1976 vitamin and mineral amendments to the act, specifically noted that food additive regulations such as the folic acid regulation were not affected. (H.R. Rep. No. 94-1005, 94th Cong., 2d Sess. 28 (1976).) Likewise, as Congress specifically stated (*Id.*), FDA may restrict to prescription drug status high potency preparations of vitamins and minerals that are not safe for use except under the supervision of a physician. For example, under §§ 250.109 and 250.110, FDA has restricted to prescription drug status high potency preparations of vitamins A and D that are not safe for use except under the supervision of a physician. These regulations have been upheld in court. *National Nutritional Foods Assn. v. Weinberger*, 512 F.2d 638 (2d Cir. 1975), *cert. den.*, 429 U.S. 1072, 49 F. Supp. 2d 1072 (No. 73 Civ. 3143, July 2, 1975).

2. A substantial number of exceptions argued against labeling as drugs those vitamins and minerals that exceed the U.S. RDA's by 150 percent.

The Commissioner advised that the revised final regulations issued below are in accord with these exceptions. Section 125.1(h) as promulgated on August 2, 1973, had provided generally that pre-

parations containing more than the upper limit of the U.S. RDA for a vitamin or mineral as specified in § 20. (f) (1) would be deemed a drug. However, the Court of Appeals ruled this provision invalid, 504 F.2d 720-723, and the 1975 vitamin and mineral amendments to the act, 21 U.S.C. 350(a)(1)(B), provide that FDA may not classify a vitamin or mineral as a drug "solely because it exceeds the level or potency which the Secretary (FDA) determines is nutritionally rational or useful." The tentative amendments to the regulations in the May 28, 1975 document revoked paragraph (h) of § 125.1, and this paragraph no longer appears in the revised final regulations issued below.

3. Three exceptions criticized the placing of minimum potency limits on vitamins and minerals. These exceptions suggested that the public be allowed to choose for itself the amount of these nutrients it wishes to purchase regardless of how low the potency level might be.

Section 80.1(c) of the revised final regulations retains the requirement that dietary supplements shall contain in the specified daily quantity not less than the lower limit specified in § 80.1(d)(1) for the groups for which the supplement is offered (generally, 50 percent of the U.S. RDA). The Commissioner believes that it would be misleading and contrary to the public interest for a vitamin and/or mineral preparation represented as a dietary supplement to provide a vitamin or mineral in an amount insignificant for use as a dietary supplement, and Congress, in passing the 1976 vitamin and mineral amendments to the act specifically agreed: "This provision (21 U.S.C. 350 (a)(1)(A)) would not restrict the Secretary (FDA) from prescribing minimum potency levels for vitamins or minerals in such products in order to prevent the addition of insignificant or useless amounts." (H.R. Rep. No. 94-1005, 94th Cong., 2d Sess. 26 (1976).) The Commissioner has concluded that, for these vitamins and minerals for which U.S. RDA's have been established, dietary supplements should provide, in the specified daily quantity, no less than the lower limit specified in § 80.1(d)(1).

4. Several exceptions requested provisions for additional formulations of vitamin/mineral dietary supplements.

The Commissioner advises that requests for additional formulations of dietary supplements are considered in section B of this preamble. It should be noted that pursuant to the 1976 Vitamin and Mineral amendments to the act, the regulations no longer limit the inclusion of ingredients which are recognized as safe in dietary supplements which are represented for use by adults (other than pregnant or lactating women) and which are intended for ingestion in tablet, capsule, or droplet form.

5. Three exceptions argued that there should be no restriction on the potency of essential vitamins and minerals for which no U.S. RDA's have been established. One exception, however, requested that potency restrictions for such vita-

mins and minerals be established. Another exception suggested determining the "appropriate" quantity of essential nutrients without established U.S. RDA's to be included in dietary supplements.

The Commissioner reiterates that pursuant to the 1976 vitamin and mineral amendments to the act, the maximum potency of safe nutrients in dietary supplements (intended for ingestion in tablet, capsule, droplet, or other form not simulating or represented as conventional food) intended for adults (other than pregnant or lactating women) may not be restricted. This includes vitamins and minerals for which no U.S. RDA has been established. However, a vitamin or mineral should be present in a dietary supplement in a minimum amount that is useful for supplementation purposes. Minimum levels have been established by § 80.1 (c) and (d)(1) for all nutrients for which U.S. RDA's have been established. Minimum levels for nutrients for which no U.S. RDA's have been established will be proposed in a future issue of the *FEDERAL REGISTER*.

6. One exception contended that establishing minimum levels for choline, vitamin K, and manganese would be "in conflict with the spirit of § 80.1(b)(5)," which provided that the standard of identity would not apply to foods which do not contain 50 percent or more of the adult U.S. RDA, which are not represented as a dietary supplement, and which are labeled in accordance with § 1.17 (21 CFR 1.17).

Section 80.1(b)(5) (redesignated § 80.1(a)(2)(i)) was intended to allow a low potency vitamin/mineral preparation, which is not appropriate for dietary supplement use, to be sold as a food, but not as a dietary supplement, and the provision has this effect for vitamins and minerals for which U.S. RDA's have been established. The Commissioner intends to propose amendments, in a future issue of the *FEDERAL REGISTER*, to establish similar provisions for choline, vitamin K, and manganese. In the meantime, preparations providing low levels of these nutrients, which would not serve a useful purpose as a dietary supplement, may be sold simply as food preparations assuming no dietary supplement claims are made.

7. Requests were made for extensions of time for filing of applications for additional formulations and for filing of exceptions to the tentative amendments.

The Commissioner advises that a 45-day extension for filing applications for additional formulations was authorized by the July 19, 1975 notice. Although no extension was authorized beyond the original July 14, 1975 deadline for filing exceptions to the tentative amendments, all exceptions, including some received as late as October 1975, have been fully considered.

8. One exception argued that § 80.1(b)(4) (redesignated § 80.1(a)(5)) improperly placed the burden on applicants to show that amending the list of vitamin/mineral combinations "will promote honesty and fair dealing in the interest of consumers," and that this requirement exceeds the scope of the Commissioner's

authority under section 401 of the act (21 U.S.C. 341).

The Commissioner does not agree. It is appropriate to require that a petition for amendment of the standard show that the requested amendment "will promote honesty and fair dealing in the interest of consumers" because this is the criterion for promulgation of such a regulation established by Congress in section 401 of the act (21 U.S.C. 341). (However, pursuant to the new vitamin and mineral amendments to the act, the Commissioner may no longer employ section 401 of the act (21 U.S.C. 341) to limit the combination of ingredients in dietary supplements offered in tablet, capsule, or droplet form, or otherwise not in the form of conventional food, for use by adults (other than pregnant or lactating women).)

9. Three exceptions objected to the banning from dietary supplements of ingredients which are not harmful but which the Commissioner has determined are nonessential. One of these exceptions contended that the inclusion of these ingredients in dietary supplements does not mislead the public.

The Commissioner advises that the 1976 vitamin and mineral amendments to the act generally prohibit FDA from limiting the inclusion of safe ingredients in dietary supplements for adults (other than pregnant and lactating women), and that the regulations issued below have been revised to conform to the new legislation, as discussed in section E of this preamble.

10. One exception contended that consumers might be confused by the mixing of "active and inactive ingredients" in the list of ingredients for a dietary supplement. It was suggested that the ingredient list be divided into two parts, with separate subheadings for nutritive ingredients and nonnutritive ingredients, instead of listing all ingredients in descending order of predominance by weight.

The Commissioner advises that § 80.1 (i) provides a format for prominent listing of the vitamins and minerals on the principal display panel or information panel of a dietary supplement. This list of vitamins and minerals is separate from, and in addition to, the ingredient statement required by §§ 80.1(j) and 1.10 (a), which includes all the ingredients, both nutritive and nonnutritive (by natural source or chemical form) in descending order of predominance by weight. The Commissioner concludes that the comprehensive listing of all ingredients used in the manufacture of a dietary supplement in descending order of predominance by weight, in addition to, and separate from, the listing of vitamins and minerals required by § 80.1(i) is useful, appropriate, and not misleading.

11. Two exceptions stated that FDA should not classify the vitamin and mineral ingredients of dietary supplements as "food additives." They argued that vitamins and minerals sold as dietary supplements are not "added" to any food and that they should only be restricted if shown to be unsafe under conditions or

ordinary use, not merely on the basis that data establishing safety are absent.

The Commissioner does not agree. If not generally recognized as safe ("GRAS"), a vitamin or mineral ingredient in a dietary supplement is a "food additive" within the meaning of the act: Any food ingredient (including a vitamin or mineral in a dietary supplement) that is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown to be safe under the conditions of its intended use in food is a "food additive" within the meaning of section 201(s) of the act (21 U.S.C. 321(s)), and pursuant to sections 402(a)(2)(C) and 409 of the act (21 U.S.C. 342(a)(2)(C) and 343) such use is illegal in the absence of a food additive regulation approving the use.

Indeed, the Conference Report explaining the effect of the 1976 vitamin and mineral amendments to the act specifically confirms that a vitamin or mineral that is not generally recognized as safe for inclusion in a dietary supplement is properly regulated as a food additive: "Similarly, if any vitamin, mineral or other food ingredient is not generally recognized as safe by qualified experts and meets the other criteria of the definition of a food additive under section 201(s) of the act, it would be subject to regulation under section 409 of the act. If such a vitamin, mineral or other ingredient is intentionally added to a food, such food is adulterated (within the meaning of section 402(a)(2)(C) of the act) unless its use is in conformity with a regulation issued by the Secretary which prescribes the conditions under which it may be safely used or exempts it for investigational use by qualified experts." (H.R. Rep. No. 94-1005, 94th Cong., 2d Sess., 28 (1976).)

A listing of some of the vitamins, minerals, and compounds with vitamin and/or mineral properties which are generally recognized as safe (GRAS), and thus lawful for use without a food additive regulation, appears at § 121.101(d)(5) (21 CFR 121.101(d)(5)).

Furthermore, numerous food additive regulations have been promulgated in Part 121 (21 CFR Part 121) to authorize the use of certain vitamin mineral ingredients, which are food additives, in dietary supplements. For example, pantothenic acid is provided for §§ 121.1037 and 121.1123; iodine in §§ 121.1073 and 121.1149; ascorbic acid and niacin in §§ 121.1093 and 121.1141; iron in § 121.1100; folic acid in §§ 121.1125 and 121.1134; and vitamin B₁₂ in § 121.1136.

12. One exception objected to the statement in the May 29, 1975 document preamble to the tentative amendments that "Dietary sulfur is the form of various salts makes no contribution to the metabolic function of sulfur in the body." (40 FR 23246). This exception contended that unless an optimal amount of inorganic sulfate is included in the diet, harmful metabolic alterations may occur.

The quoted statement should not be read out of context. The Commissioner did not state or mean to imply that in-

gested sulfur-containing compounds do not enter into metabolic reactions. Sulfur-containing substances, which commonly occur in foods (e.g., amino acids, protein, the vitamins biotin and thiamine, sulfates, and a host of organic compounds in eggs, meats, milk, and other foods in which sulfur is complexed), may be catabolized and the sulfur may be released in the tissues or organs in a form which the body can use for synthesizing vital or useful substances such as insulin and cartilage. The point, however is, that a diet adequate in protein will supply sufficient sulfur for the body to perform these functions. The Commissioner reemphasizes that humans will not benefit nutritionally from deliberate supplementation of the diet with sulfates, be they inorganic salts or any other compound or complex of sulfur.

13. Several exceptions contended that since every individual has his or her own unique body chemistry, U.S. RDA's for large classes of individuals are imprecise, misleading and/or conceptually inadequate for regulating vitamin/mineral preparations.

The appropriateness of using the NAS/NRC RDA's as a basis for the U.S. RDA's and the appropriateness of the latter for regulating and informing consumers about the nutritional value of vitamin/mineral preparations were thoroughly discussed documents in the FEDERAL REGISTER of January 19, 1973 (38 FR 2125-2132, 2143-2150, 2152-2162) and August 2, 1973 (38 FR 20768-20778, 20780-20790, 20745). The Court of Appeals, while remanding the regulations to FDA for certain further action, nevertheless affirmed FDA's authority to use U.S. RDA's to regulate the labeling and composition of dietary supplements. Expert testimony at the reopened hearing in November 1975, as discussed in section C of this preamble, reconfirmed the validity and usefulness of RDA's as basis for the U.S. RDA's.

14. Another exception asked that FDA update the U.S. RDA's to reflect changes made in the eighth edition of the NAS/NRC "Recommended Dietary Allowances" (1974). It was contended that such a revision would significantly decrease costs and that it is necessary to protect FDA's scientific integrity.

The Commissioner recognizes that the eighth edition of "Recommended Dietary Allowances" contains several changes in RDA values. These changes include a reduction in the total number of age groups for which values are given (to 10), reductions in the highest RDA values for each of 6 nutrients in each age group, a small increase in the highest value for riboflavin, and establishment of RDA's for zinc. The Commissioner has carefully considered the significance of these changes in terms of the function of U.S. RDA's and their relevance to consumers. The Commissioner has concluded that amending the U.S. RDA's at this time to accommodate these changes would not be in the interest of consumers. (The new RDA's for zinc are consistent with the U.S. RDA's already established for zinc.) However, it is reasonable to anticipate

changes in the existing U.S. RDA's to reflect changes in the RDA's when the latter are next revised. The Commissioner does not believe that the requested revision of the U.S. RDA's would significantly decrease the cost of foods to consumers.

15. A food retailer requested that paragraph (c) (5) of § 80.1 (§ 80.1(a) (2) (v) of this final regulation) be changed to remove the word "attains." The comment noted that this paragraph provides that § 80.1 applies if an added vitamin or mineral per single serving "attains or exceeds 50 percent" of the U.S. RDA. It recommended that the word "attains" be removed "to keep the arithmetic simple for the consumer" by allowing a food to provide and declare 50 percent of the U.S. RDA without triggering the requirements of § 80.1.

This same request was denied when FDA's nutrition labeling regulations were promulgated in the FEDERAL REGISTER of March 14, 1973 (38 FR 6251) (see No. 13 at 38 FR 6952), and the Commissioner is not aware of any evidence to indicate that change is needed. This issue is not really one of "simple arithmetic" for the consumer; rather, the issue is whether a preparation which provides 50 percent of the U.S. RDA per serving is more in the nature of a dietary supplement or of an ordinary food. The Commissioner concludes that such a product is appropriately regulated as a dietary supplement.

16. One exception requested that the meaning of "raw agricultural commodities" in paragraph (c) (6) of § 80.1 (now redesignated as § 80.1(a) (2) (vi)) be clarified. Another comment argued that marine products as well as raw agricultural commodities ought to be exempted from § 80.1 and that the phrase "including marine products" should be reinstated in § 80.1 (c) (6), thereby exempting them on the same terms they were exempted before the May 28, 1975 amendment of § 80.1.

The Commissioner advises that the term "raw agricultural commodity" is defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(r)) as "any food in its raw or natural state." The term "any food" in section 201(r) includes marine products. The phrase "in its raw or natural state" means that nothing has been done to the article, other than superficial treatment such as washing its surface, to change the article physically or chemically before marketing.

17. A request was made by a manufacturer of vitamin products that the interim lower limit of 0.05 mg established for biotin in footnote 4 to the table in § 80.1(f) (1) (now redesignated as § 80.1(d) (1)) be extended past the December 31, 1978 deadline. The exception sought this extension due to the delays in implementation of regulations for combination vitamin/mineral products. This same exception also requested that a change be made in the final revisions to allow the use of "vitamin H" as a synonym for biotin.

The Commissioner has determined there is no evidence that would justify an extension of the interim lower limit

of 0.05 mg for biotin. This extension was originally granted in 1973 pursuant to evidence that insufficient amounts of biotin were available to producers of dietary supplements. The extension was for a period in excess of 3 years, which was a reasonable amount of time in which the author of this exception admits has resulted in increased availability of biotin. Furthermore, it should be noted that this is an optional ingredient in dietary supplements and that the increased lower limits of biotin (0.075 mg for children under 4, 0.15 mg for adults and children 4 or more years of age, and 0.3 mg for pregnant or lactating women) are not unreasonable.

The Commissioner has further determined that the use of "vitamin H" as a synonym for biotin will not be sanctioned. "Vitamin H" is an obsolete term that never truly described a discrete chemical entity; it was used to denote an uncharacterized semipure substance isolated from natural sources with vitamin-like biological activity in a test organism. It has not been accepted in the nutritional literature as an alternate name for biotin. Furthermore, the Commissioner desires to encourage use of uniform nomenclature in label declaration of nutrients, in order to facilitate consumer comparisons between products. The use in labeling of "vitamin H" as an alternate name for biotin would serve no useful public purpose.

18. One exception asked that the regulations be revised to include an express proviso authorizing the sale of "imitation" dietary supplements.

The Commissioner believes that it would be misleading to sell a vitamin/mineral preparation which fails to comply with § 80.1 as an "imitation dietary supplement." Furthermore, the Commissioner notes that this exception was filed before passage of the 1976 vitamin and mineral amendments to the act. The purpose of this exception was to seek means of marketing vitamin/mineral preparations that do not conform to FDA's definition and standard of identity (§ 80.1). Since the new legislation generally prohibits FDA from limiting the inclusion of ingredients or maximum potency of vitamins and minerals in dietary supplements for adults (other than pregnant or lactating women), the purpose of the exception largely has been achieved by the new legislation.

19. One exception felt that more detailed labeling should be required to inform consumers of the composition and quality of dietary supplements. It was suggested in this exception that all ingredients be listed on the label, that the weight of each ingredient be disclosed, and that the expiration date and potency of the ingredients at the time of expiration be provided.

The Commissioner advises that § 80.1(d) (1) already requires that labels of dietary supplements list each nutrient supplied in terms of U.S. RDA's and in terms of milligrams (or other appropriate units of measure as specified in § 80.1(d) (1)). Expiration dating for nutrients subject to deterioration is provided for in § 80.1(1).

20. Another exception objected to the wording of the Commissioner's May 28, 1975 tentative amendment of § 125.2(b) (2). It was suggested that instead of the present proviso regarding iron requirements, and in accordance with the Court of Appeals' decision, the following clause be inserted in parentheses after the first word of paragraph (b) (2): "Except for the iron requirements of infants, children, and women of child-bearing age."

The Commissioner has determined that the present wording of § 125.2(b) (2) accurately reflects his intention and the requirements of the Court, which found that, based upon the existing record, women of child-bearing age and children do have difficulty in obtaining iron requirements from conventional foods and that therefore a general statement to that effect is not misleading and should be allowed (504 F.2d 692).

21. One exception opposed tentative § 125.3(c), which would have required that a labeling representation that a vitamin or mineral is derived from a certain source be accompanied by a declaration of the percentage of the vitamin or mineral provided by that source.

Although the Commissioner believes that § 125.3(c) was a desirable provision, he has concluded that it was not within the scope of the remand instructions of the Court of Appeals, and accordingly the provision has been deleted from the regulations issued below. It should be noted, however, that section 403(a) of the act continues to prohibit the sale of products with false or misleading labeling. This includes a product represented as containing significant quantities of a vitamin or mineral from a particular source (e.g., "Vitamin C from Rose Hips"), but which in fact contains only insignificant quantities of the vitamin or mineral from that source.

22. The same exception asked that § 125.2(b) (2) be expanded to include vitamin B, folacin, and magnesium because, it asserted, adequate supplies of these nutrients are generally not found in the food supply.

The Commissioner is not aware of any substantial evidence to indicate that a balanced diet of ordinary foods cannot supply adequate amounts of these three nutrients.

E. 1976 AMENDMENTS TO FEDERAL FOOD, DRUG, AND COSMETIC ACT

On April 22, 1976, the President signed new legislation which amends the Federal Food, Drug, and Cosmetic Act so as to restrict FDA's authority to limit the inclusion of ingredients and maximum potency of vitamins and minerals in dietary supplements which are offered for use by adults, other than pregnant or lactating women, and are recognized as safe. (Pub. L. 94-278, 94th Congress (Title V); codified as 21 U.S.C. 350.)

Products subject to the legislation. The restrictions in the new legislation apply only to "a food for humans which is a food for special dietary use—(A) which is or contains any natural or synthetic vitamin or mineral, and (B) which—(i) is intended for ingestion in

tablet, capsule, or liquid form, or (ii) if not intended for ingestion in such form, does not simulate and is not represented as conventional food (e.g., vitamin enriched bread, milk, breakfast cereals, etc.) and is not represented for use as a sole item of a meal or of the diet." (The legislation provides that "a food shall be considered as intended for ingestion in liquid form only if it is formulated in a fluid carrier and it is intended for ingestion in daily quantities measured in drops or similar small units of measure.")

The legislation specifically provides that it does not apply to a vitamin/mineral preparation "represented for use by individuals in the treatment or management of specific diseases or disorder, by children or by pregnant or lactating women." (The term "children" is defined as "individuals who are under the age of twelve years.") Congress, recognizing the vulnerability of children under 12 years of age and pregnant and lactating women, stated in their Joint Conference Report accompanying this legislation, at page 28, that "it is intended that the Secretary retain full authority to promulgate regulations designed to assure that unsuitable or inappropriate vitamin and mineral preparations are not inadvertently administered to individuals in these vulnerable groups." Labeling provisions designed for this purpose will be proposed in a future issue of the FEDERAL REGISTER.

Thus, in general, the legislation applies to tablets, capsules, droplets, and similar preparations not resembling ordinary foods, which are sold as dietary supplements of one or more vitamins or minerals for use by adults other than pregnant or lactating women.

Definition of "special dietary use." The new legislation defines the term "special dietary use" for purposes of identifying the vitamin/mineral preparations to which it applies. This definition differs in certain particulars from the definition of the term in § 125.1(a) of the August 2, 1973 regulations. Since the definition in the new legislation applies only to those vitamin/mineral preparations subject to the new legislation, the Commissioner could retain the definition published in the August 2, 1973 regulations for other preparations (e.g., dietary supplements represented for use by individuals in the treatment or management of specific diseases or disorders, by children, or by pregnant or lactating women; vitamin/mineral preparations which simulate conventional food; etc.). However, the Commissioner concludes that no useful purpose would be served by such action, which would result in two slightly different definitions of "special dietary use," one applicable to preparations subject to the new legislation and the other applicable to other foods for special dietary use. Accordingly, the final revised regulations adopt the definition of "special dietary use" contained in the new legislation for all foods governed by Part 125.

Effect of the new legislation. The new legislation provides that FDA may not rely on its authority under section 401 of the act (21 U.S.C. 341) to establish

standards of identity for foods or its authority under sections 201(n) and 403 of the act (21 U.S.C. 321(n) and 343) to prevent misbranding of foods, to establish maximum limits on the potency of any vitamin or mineral, or to restrict the combination or number of any vitamin, mineral, or other ingredient in a preparation to which it applies.

FDA retains authority to require that a vitamin or mineral included in a dietary supplement be present in an amount appropriate for dietary supplementation, i.e., to establish minimum potency requirements so that preparations providing quantities of a vitamin or mineral insufficient for supplementation purposes may be prohibited.

The new legislation provides that ingredients that are not vitamins or minerals (e.g., rutin, other bioflavonoids, or para-aminobenzoic acid) may not be listed in the labeling of a preparation to which the legislation applies except as a part of a list of all ingredients in the product (i.e., the list which includes all ingredients used in the manufacture of the product, including preservatives, stabilizers, flavors, sweeteners, colors, carriers, bases, etc., in descending order of predominance by weight). The new legislation also provides that the labeling and advertising for any food to which it applies may not give prominence to or emphasize ingredients which are not vitamins, minerals, or represented as a source of vitamins or minerals.

Restrictions on formulations because of safety considerations. The new legislation does not restrict FDA's authority to limit the composition of dietary supplements on the basis of safety considerations. For example, if use of a vitamin or mineral is not generally recognized as safe, within the meaning of section 201(s) of the act (21 U.S.C. 321(s)), it may be used only in a manner consistent with an approving food additive regulation and pursuant to sections 402 (a) (2) (C) and 409 of the act (21 U.S.C. 342(a) (2) (C), and 343). Thus, FDA has promulgated a food additive regulation limiting, for reasons of safety, the amount of the vitamin folic acid which may be used in dietary supplements in accordance with § 121.1134 (21 CFR 121.1134). Likewise, pursuant to section 503(b) of the act (21 U.S.C. 353(b)), FDA has restricted to prescription drug status high potency preparations of vitamins A and D which are not safe for use except under the supervision of a physician, as provided by §§ 250.109 and 250.110 (21 CFR 250.109 and 250.110). (These regulations have been sustained in court. *National Nutritional Foods Assn. v. Weinberger*, 512 F.2d 638 (2d Cir. 1975), ____ F. Supp. ____ (No. 73 Civ. 3442, July 2, 1976).)

False claims. The new legislation does not permit false or misleading claims to be made for a vitamin/mineral preparation. If labeling is false or misleading in any particular, the product will be deemed to be misbranded pursuant to sections 201(n) and 403(a) of the act (21 U.S.C. 321(n) and 343(a)).

Drug claims. The legislation also provides that FDA may not classify a vitamin/mineral preparation as a drug "solely because it exceeds the level of potency which the Secretary (FDA) determines is nutritionally rational or useful." However, pursuant to section 201 (g) (1) (B) of the act (21 U.S.C. 321(g) (1) (B)), if the labeling or advertising for a vitamin/mineral preparation makes drug claims, the preparation is a drug subject to the drug requirements of the act.

Advertising of vitamin/mineral preparations. The new legislation gives FDA limited new authority over the advertising of vitamin/mineral preparations. Generally, the Federal Trade Commission (FTC) has exclusive authority over the advertising of food. Under the new legislation, FDA may pursue seizures and injunctions under the act when the advertising of a vitamin/mineral preparation is misleading in a material respect. However, before taking such action, FDA is in most instances required under the new legislation to notify FTC of a suspected advertising violation. If within 90 days FTC or the Attorney General takes action against the advertising under the Federal Trade Commission Act, FDA may not institute action under the Federal Food, Drug, and Cosmetic Act. (This requirement of prior notice to FTC and deferral to action under the Federal Trade Commission Act does not apply if FDA action against the advertising "is required to eliminate an imminent hazard to health.")

Summary. The regulations promulgated below have been revised to comply with the new amendments to the Federal Food, Drug, and Cosmetic Act as well as the remand directions of the Second Circuit. This has been accomplished by incorporating in § 125.1 the legislative definition of "special dietary use", as discussed above, and by adding new paragraph (e) to § 80.1 which provides that products subject to the new vitamin/mineral legislation are not subject to the maximum potency limits and the limits on inclusion of ingredients otherwise imposed on dietary supplements by §§ 80.1 and 125.2(b) (5). (A cross-reference to § 80.1(c) has been added to § 125.2(b) (5).) The maximum potency limits and limits on inclusion of ingredients established by § 80.1 remain applicable to preparations not subject to the new vitamin/mineral legislation, e.g., dietary supplements offered for use by infants or by pregnant or lactating women.

F. OTHER MATTERS

(1) **Reorganization and recodification of regulations for clarity.** In addition to substantive revisions of the regulations discussed in sections B, D, and E above, the Commissioner has reorganized the regulations to improve clarity. For example: § 80.1 has been expanded; paragraphs (a) through (n) have been given

descriptive subject headings; and various provisions of the regulation have been relocated under the appropriate headings. Thus, the list of articles not subject to the definition and standard of identity has been given an appropriate heading and moved forward to § 80.1(a) (2), where it follows immediately after § 80.1(a) (1), which, under appropriate heading, describes the articles that are subject to the definition and standard. (In the regulations as published August 2, 1973, the articles not subject to the definition and standard were listed at both paragraphs (b) (5) and (e) of § 80.1, and the exemptive provision at paragraph (b) (5) appeared under a heading which did not accurately characterize the provision.)

(2) **Effective date.** The Commissioner recognizes that the new regulations are likely to require extensive relabeling (as well as some reformulation for dietary supplements represented for use by infants, children, or pregnant or lactating women), and he intends to allow reasonable time for compliance.

On the other hand, the new vitamin and mineral legislation requires extensive labeling revisions even in the absence of the new FDA regulations. For example, the new legislation provides that a preparation to which it applies may not list its ingredients that are not vitamins and minerals except as a part of a list of all the ingredients and in accordance with applicable regulations under section 403 of the act (21 U.S.C. 343), i.e., §§ 1.10 and 1.10a (21 CFR 1.10 and 1.10a). Congress provided that the labeling requirements of the new legislation "shall take effect 180 days after the date of enactment of this Act." The new legislation was enacted April 22, 1976, and thus it will become effective October 19, 1976. The Commissioner cannot postpone enforcement of an act of Congress without just and compelling cause.

In consideration of the extensive relabeling that will be required for compliance with the new regulations, the Commissioner has determined to postpone the effective date of the new regulations until January 1, 1978, i.e., he will apply the regulations to products that are initially introduced into interstate commerce on or after that date. Voluntary compliance may begin immediately.

To facilitate uniform labeling changeovers by industry, the Commissioner advises that he will similarly postpone enforcement of the labeling requirements of the new vitamin and mineral legislation, i.e., that he will apply the labeling requirements of the new legislation to products that are initially introduced into interstate commerce on or after January 1, 1978. Again, voluntary compliance may begin immediately.

(3) **Judicial review.** In promulgating these revised regulations, the Commis-

sioner has endeavored to comply conscientiously with the remand direction of the Court of Appeals. Furthermore, recognizing the will of Congress, the Commissioner has moved expeditiously also to amend the regulations so that they no longer purport to limit the inclusion of ingredients or maximum potency of vitamins or minerals in preparations subject to the new legislation. The Commissioner believes that there is no valid pretext for further litigation over the propriety of these regulations. However, if anyone should believe that the new regulations fail to comply with the remand directions of the Court of Appeals, with due consideration to Congress' new requirements, the Commissioner asks that any such person seek relief from the U.S. Court of Appeals for the Second Circuit forthwith so that the matter can be settled as quickly as possible. The regulation of dietary supplements has been a matter of controversy for several years, with almost constant activity and uncertainty in administrative, judicial, and legislative arenas. There is need now for some finality and certainty in the rules to govern this subject.

The Commissioner has reviewed these final revised regulations and concludes that they will not significantly affect the quality of the human environment and that an environmental impact statement is not required. A copy of the environmental assessment is on file with the Hearing Clerk, Food and Drug Administration, Rm. 4-C5, 5600 Fishers Lane, Rockville, MD 20852.

Therefore, in accordance with the foregoing discussion, and pursuant to the Federal Food, Drug, and Cosmetic Act (secs. 201(n), 401, 403 (a) and (j), 411, 701 (a) and (e), 52 Stat. 1031, 1036-1043, 1055, 70 Stat. 919, 60 Stat. 416-417 (21 U.S.C. 321(n), 341, 343 (a) and (j), 350, 371 (a) and (e))), and under authority delegated to the Commissioner (21 CFR 5.1) (recodification published in the FEDERAL REGISTER of June 15, 1976 (41 FR 24262)), Chapter I of Title 21 of the Code of Federal Regulations is amended as follows:

In Part 80 by revising § 80.1 to read as follows:

§ 80.1 Dietary supplements of vitamins and minerals.

(a) **General provisions—(1) Articles subject to this regulation: "dietary supplements."** The dietary supplements of vitamins and or minerals for which definitions and standards of identity are prescribed by this section are prepared and offered as tablets, capsules, waters, or other similar uniform units; in powder, granular, flake, or liquid form; or in the physical form of conventional foods; and purport to be or are represented for special dietary use by man to supple-

ment his diet by increasing the total dietary intake of one or more of the essential vitamins and/or minerals specified in paragraph (d) of this section. The dietary supplements of vitamins and/or minerals are henceforth referred to as "dietary supplements" in this section.

(2) *Articles not subject to this regulation.* This section does not apply to:

(i) Any food which contains or consists of any vitamin or mineral listed in § 125.1(b)(1) of this chapter, or any combination thereof, provided that all of the following requirements are met: (a) No such nutrient is contained at a level of 50 percent or more of the adult U.S. RDA per serving for that nutrient, (b) no direct or implied representation is made on the label, in labeling, or in advertising that the product is a dietary supplement or is adequate or appropriate for supplementing the daily diet with essential nutrients, and (c) the product is labeled pursuant to § 1.17 of this chapter.

(ii) Foods the composition of which is defined by other regulations, e.g., other foods for which definitions and standards of identity or nutritional quality guidelines have been promulgated, or statutes.

(iii) Any food represented for use as the sole item of a meal or of the diet.

(iv) Foods represented for use solely under medical supervision to meet nutritional requirements in specific medical conditions.

(v) Conventional foods to which one or more nutrient(s) listed in paragraph (d)(1) of this section are added to improve nutritional quality, unless the total level, including any naturally occurring amounts, of any such added vitamin or mineral per single serving attains or exceeds 50 percent of the U.S. Recommended Daily Allowance (U.S. RDA) for adults and children 4 years or more of age as specified in § 125.1(b)(1), in which case the provisions of both this section and § 1.17 shall apply. If the provisions of both this section and § 1.17 of this chapter apply to a food, the labeling of such food shall conform to the labeling established in this section except that the labeling established in § 1.17(c), including the order for listing vitamins and minerals established in § 1.17(c)(7)(iv), shall be used in lieu of the labeling established in paragraph (d)(1) of this section.

(vi) Raw agricultural commodities.

(vii) A food with nutrients restored to pre-processing levels or added pursuant to § 1.8(c) of this chapter so that it is not nutritionally inferior to the food for which it substitutes and which it resembles.

(3) *Enforcement.* Any food product that meets the definition of a dietary supplement in paragraph (a)(1) of this section and which is not subject to any of the exemptions set forth in paragraph (a)(2) of this section and which fails to comply with the requirements of this section, including a multi-component supplement not subject to paragraph (e) of this section which offers an added vitamin or mineral not permitted by this section or which offers a greater potency of any vitamin or mineral than is permitted by this section, will be deemed to be in violation of section 403(g) of the Federal Food, Drug, and Cosmetic Act (hereafter "the act"), which provides that a food shall be deemed to be misbranded if it purports to be or is represented as a food for which a definition and standard of identity has been prescribed, unless it conforms to the definition and standard.

(4) *Other requirements of law.* Compliance with the requirements of this section does not exempt a dietary supplement from other requirements of any other applicable regulations, whether or not cross-referenced herein.

(5) *Amendments to this standard.* Amendment of the permissible combinations of vitamins and/or minerals, as established in paragraph (b) of this section, or of the permitted range of potency for any vitamin(s) or mineral(s) in a dietary supplement as established in paragraph (c) of this section, or any other amendments to this section, may be proposed by the Commissioner of Food and Drugs on his own initiative or upon petition by an interested person in accordance with the procedure set forth in Part 2 of this chapter. Any such petition shall be submitted in the form set forth in § 2.65 of this chapter and shall include data to show that such amendment will promote honesty and fair dealing in the interest of consumers.

(b) *Inclusion of vitamins and minerals in dietary supplements.* Except as provided in paragraph (e) of this section: (1) A dietary supplement consisting of more than one vitamin or mineral shall contain only those vitamins and/or minerals listed in paragraph (d)(1) of this section and shall be offered for its vitamin and/or mineral content only in the following combinations, with the provision that any vitamin or mineral defined as optional in paragraph (d)(1) of this section may be omitted:

- (i) All vitamins and minerals.
- (ii) All vitamins.
- (iii) All minerals.
- (iv) All vitamins and the mineral iron.
- (v) A dietary supplement of vitamins A, D, and C, represented for use by in-

fants and/or children under 4 years of age, composed of vitamin A, vitamin D and vitamin C. Vitamin B₁₂ and/or iron may be included as optional ingredients in such a preparation: *Provided*, That inclusion of the optional ingredients vitamin D and/or phosphorus in the dietary supplements identified in paragraph (b)(1)(i), (ii), (iii) or (iv) of this section does not require inclusion of any additional optional ingredients. Inclusion of the optional ingredients biotin and pantothenic acid and/or copper and zinc in such products does not require inclusion of vitamin D and/or phosphorus when the latter two nutrients are optional. Inclusion of any of the other optional ingredients (biotin or pantothenic acid for vitamins and copper or zinc for minerals) in such products requires the inclusion of both such optional ingredients if the product is a multi-vitamin or multimineral supplement, and requires the inclusion of all four such ingredients if the product is a multi-vitamin and multimineral supplement; and: *Provided further*, That folic acid is optional for liquid dietary supplements because of instability of the vitamin in liquid preparations. A liquid dietary supplement represented as a "multivitamin" preparation but not containing folic acid shall bear the following statement on the label: "This product does not contain the essential vitamin folic acid," which shall immediately follow the listing of vitamins and minerals as prescribed in paragraph (i) of this section.

(2) A dietary supplement may also be composed of a single vitamin or mineral.

(c) *Potency of vitamins and minerals in dietary supplements.* (1) Except as provided in paragraph (e) of this section, and subject to good manufacturing practices, dietary supplements shall contain in the specified daily quantity not less than the lower limit nor more than the upper limit of any nutrient specified in paragraph (d)(1) of this section for the groups for which the supplement is offered.

(2) For the purposes of this section, the term "daily quantity" means the quantity of a dietary supplement that shall be specified in the labeling for consumption in a period of 1 day, and which shall be an amount or number of units reasonably suitable for and practicable of consumption in 1 day.

(d) *U.S. Recommended Daily Allowance.* (1) The following table sets forth the permissible qualitative and quantitative composition of dietary supplements of vitamins and/or minerals for purposes of paragraphs (b) and (c):

U.S. recommended daily allowances (U.S. RDA's) and permissible compositional ranges for dietary supplements of vitamins and minerals¹

Unit of measurement	Children under 4 years of age ²			Adults and children 4 or more years of age			Pregnant or lactating women		
	Lower limit	U.S. RDA	Upper limit	Lower limit	U.S. RDA	Upper limit	Lower limit	U.S. RDA	Upper limit
Vitamins—Mandatory:									
Vitamin A..... International units.....	1,250	2,500	2,500	2,500	4,000	5,000	5,000	2,000	5,000
Vitamin D ³ do.....	200	400	400	15	30	45	30	400	400
Vitamin E..... do.....	5	10	15	15	30	45	30	30	60
Vitamin C..... Milligrams.....	20	40	60	30	60	90	60	60	120
Folic acid ⁴ do.....	.1	.2	.3	.2	.4	.4	.4	.8	.5
Thiamine..... do.....	.35	.70	1.05	.75	1.50	2.25	1.50	1.70	3.00
Riboflavin..... do.....	.4	.8	1.2	.8	1.7	2.6	1.7	2.0	3.4
Niacin..... do.....	4.8	9.0	13.8	10.0	20.0	30.0	20.0	20.0	40.0
Vitamin B ₆ do.....	.35	.70	1.05	1.00	2.00	3.00	2.00	2.50	4.00
Vitamin B ₁₂ Micrograms.....	1.5	2.0	4.5	2.0	6.0	8.0	2.0	8.0	12.0
Optional:									
Vitamin D..... International units.....	.075	.150	0.225	200	400	400	.250	.250	.600
Biotin..... Micrograms.....	2.5	8.0	7.5	5.0	10.0	15.0	10.0	10.0	20.0
Pantothenic acid..... do.....	2.5	8.0	7.5	5.0	10.0	15.0	10.0	10.0	20.0
Minerals—Mandatory:									
Calcium..... Grams.....	.125	.800	1.200	.125	1.000	1.500	.125	1.300	2.000
Phosphorus ⁵ do.....	.125	.800	1.200	.125	1.000	1.500	.125	1.300	2.000
Iodine..... Micrograms.....	35	70	105	75	150	225	150	150	250
Iron..... Milligrams.....	5	10	15	9	18	27	18	18	60
Magnesium..... do.....	40	200	300	100	400	600	100	450	800
Optional:									
Phosphorus ⁶ Grams.....	.5	1.0	1.5	1.0	2.0	3.0	1.0	1.500	2.000
Copper..... Micrograms.....	4.0	8.0	12.0	7.5	15.0	22.5	7.5	15.0	30.0
Zinc..... do.....	4.0	8.0	12.0	7.5	15.0	22.5	7.5	15.0	30.0

¹ When labeled for use by infants, a dietary supplement shall contain not less than the lower limit designated for a nutrient in this set of columns, nor more than 100 percent of the infant U.S. RDA for a nutrient as presented in sec. 125.1(b) of this chapter except that the level of Biotin, when used, shall be 0.65 mg daily recommended quantity.

² Optional for adults and children 4 or more years of age.

³ Optional for liquid products.

⁴ Optional for pregnant or lactating women. When present, the quantity of phosphorus may be not greater than the quantity of calcium.

(2) The U.S. Recommended Daily Allowances (U.S. RDA's) have been derived by the Food and Drug Administration from the "Recommended Dietary Allowances," published by the Food and Nutrition Board, National Academy of Sciences/National Research Council, and are subject to amendment as more

knowledge on human nutrient requirements becomes available.

(3) For determining the percentage of the U.S. RDA present in a dietary supplement, the quantitative content of the following vitamins shall be calculated in terms of the following chemically identifiable reference forms:

Reference form

Vitamin	Name	Empirical formula	Molecular weight
Vitamin C.....	L-Ascorbic acid.....	C ₆ H ₈ O ₆	176.2
Folic acid.....	Pteroyl mono-L-glutamic acid.....	C ₂₀ H ₂₆ N ₅ O ₇	441.41
Thiamine.....	Thiamine chloride hydrochloride.....	C ₁₂ H ₁₇ ClN ₄ OS.HCl	337.28
Riboflavin.....	Riboflavin.....	C ₁₇ H ₂₀ N ₄ O ₆	376.37
Niacin.....	Nicotinic acid.....	C ₆ H ₅ NO ₂	123.11
Vitamin B ₆	Pyridoxine.....	C ₈ H ₉ NO	169.15
Vitamin B ₁₂	Cyanocobalamin.....	C ₆₃ H ₈₈ CoN ₁₄ O ₁₄ P	1,355.49
Biotin.....	Biotin.....	C ₁₀ H ₁₆ N ₂ O ₃ S	244.31
Pantothenic acid.....	D-Pantothenic acid.....	C ₉ H ₁₇ NO ₆	219.23

(4) In addition to the nutrients listed in paragraph (d)(1) of this section, other vitamins and minerals recognized as essential or probably essential in human nutrition in their biologically active forms but for which no U.S. RDA's have been established are: vitamin K, choline, and the minerals chlorine, chromium, fluorine, manganese, molybdenum, nickel, potassium, selenium, silicon, sodium, tin, and vanadium.

(c) **Exemption from limitations on inclusion of ingredients and from maximum potency restrictions for certain dietary supplements.** (1) Pursuant to section 411(a)(1) of the act, the limitations established by paragraphs (b) and (d) of this section and by § 125.2(b)(5) of this chapter with respect to the inclusion of vitamins, minerals, and other ingredients in dietary supplements, and the maximum limits on potency established by paragraphs (c) and (d) of this section shall not apply to a food for special dietary use, defined in § 125.1(a)(1) of

this chapter, which is or contains any vitamin or mineral and which complies with the following criteria:

(i) The preparation is intended for ingestion in tablet, capsule, or liquid form, or, if not intended for ingestion in such a form, does not simulate and is not represented as conventional food and is not represented for use as a sole item of a meal or of the diet; and

(ii) The preparation is not represented for use by individuals in treatment or management of specific diseases or disorders, by children, or by pregnant or lactating women.

(2) For purposes of paragraph (e)(1) of this section, a food shall be considered as intended for ingestion in liquid form only if it is formulated in a fluid carrier and it is intended for ingestion in daily quantities measured in drops or similar small units of measure; and the term "children" means individuals who are under the age of 12 years.

(3) The exemption provided by section 411(a)(1) of the act and paragraph (e)(1) of this section does not apply to minimum potency requirements established by this section. Whenever a vitamin or mineral for which a U.S. RDA has been established is included in a dietary supplement, the supplement shall provide in the recommended daily quantity at least the lower potency limit for the vitamin or mineral established by the table in paragraph (d)(1) of this section.

(4) The exemption provided by section 411(a)(1) of the act and paragraph (e)(1) of this section does not apply to restrictions on maximum potency imposed by the act or by regulations for reasons of safety under paragraph (f) of this section.

(f) **Restrictions on maximum potency of vitamins and minerals for reasons of safety.** Restrictions of the maximum potency of a vitamin or mineral may be imposed for reasons of safety by the act or by regulation. For convenience, certain restrictions are cross-referenced below:

- (1) Vitamin A—See § 250.109.
- (2) Vitamin D—See § 250.110.
- (3) Folic acid—See § 121.1134.
- (4) Iodine—See §§ 121.1073 and 121.1149.
- (5) Copper—See § 121.101(d)(5).
- (6) Fluorine—See § 121.10.
- (7) Potassium—See § 201.306.

(8) Any vitamin or mineral which is included in a dietary supplement and which is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown to be safe under the conditions of its intended use is a food additive within the meaning of section 201(s) of the act, and pursuant to sections 402(a)(2)(C)

and 409 of the act such inclusion is illegal in the absence of a food additive regulation approving such inclusion. A listing of some of the vitamins, minerals, and compounds with vitamin and/or mineral properties which are generally recognized as safe, and which thus may lawfully be included in a dietary supplement without a food additive regulation, appears at § 121.101(d)(5).

(g) *Acceptable ingredient sources for dietary supplements:* (1) A vitamin or mineral used in a dietary supplement may be supplied by any suitable substance which is not a food additive as defined in section 201(s) of the act; or if it is a food additive as so defined, it shall be used in conformity with regulations established pursuant to section 409 of the act.

(2) Any safe and suitable substance may be used as preservative, stabilizer, flavor, sweetener, color, seasoning, carrier, base, or vehicle, or to facilitate preparation of vitamin or mineral substances. A dietary supplement shall be prepared so that any such substance contained therein does not exceed the amount reasonably required to accomplish its intended physical or technical effect, and so that the biological availability of the vitamin(s) and mineral(s) is not impaired by the presence of such substance. Any such substance shall not be a food additive or color additive as defined in section 201 (s) or (t) of the act; or if it is a food additive or color additive as so defined, it shall be used in conformity with regulations established pursuant to section 409 or 706 of the act.

(h) *Nomenclature.* (1) The name of a dietary supplement shall consist of a term descriptive of the vitamin and/or mineral composition of the product, as established in paragraph (h)(2) of this section, together with a phrase or phrases designating the group(s) for which the supplement is intended, as established in paragraph (h)(3) of this section, e.g., "multivitamin and multimineral supplement for children under 4 years of age"; "dietary supplement of vitamin C and E for adults". The name of the dietary supplement shall appear prominently and conspicuously on the principal display panel(s) of the label. The letters or phrase(s) designating the consumer group(s) for which the product is represented, shall be no less than one-third the size of those used in the term descriptive of the composition of the product. In addition to the name prescribed by this paragraph, a dietary supplement may be labeled with a proprietary name: *Provided*, That it is not false or misleading in any particular.

(2) The terms used to describe the vitamin and/or mineral composition of dietary supplements shall be as follows:

(i) "Multivitamin and multimineral supplement" for a dietary supplement containing all vitamins and minerals identified as "mandatory," for the group(s) for which the supplement is offered, in the table in paragraph (d)(1) of this section.

(ii) "Multivitamin supplement" for a dietary supplement containing all vitamins identified as "mandatory," for the group(s) for which the supplement is offered, in the table in paragraph (d)(1) of this section.

(iii) "Multimineral supplement" for a dietary supplement containing all minerals identified as "mandatory," for the group(s) for which the supplement is offered, in the table in paragraph (d)(1) of this section.

(iv) "Multivitamin and iron supplement" or "multivitamin supplement with iron" for a dietary supplement containing all vitamins identified as "mandatory," for the group(s) for which the supplement is offered, in the table in paragraph (d)(1) of this section and the mineral iron.

(v) "----- supplement" for a dietary supplement containing a single vitamin or mineral listed in paragraph (d) of this section (the blank to be filled in with the name of the vitamin or mineral).

(vi) "Dietary supplement of vitamins A, D, and C" for a preparation complying with paragraph (b)(1)(v) of this section, provided that if vitamin E is included, the term shall read " * * * vitamins A, D, C, and E * * * " and that if iron is included, the term shall conclude with " * * * with iron" or " * * * and iron."

(vii) If, pursuant to section 411(a)(1) of the act and paragraph (e)(1) of this section, the dietary supplement contains more than one vitamin or mineral but does not meet the criteria for any of the preparations identified in paragraph (h)(2) (i) through (vi) of this section, the preparation shall bear a term that is accurately descriptive of its vitamin and/or mineral composition, e.g., "dietary supplement of vitamins A, C, and E." The term "multivitamin" shall not be used to describe a product which fails to provide all of the vitamins identified as "mandatory," for the group(s) for which the supplement is offered, in the table in paragraph (d)(1) of this section, except as provided in the second proviso clause of paragraph (b)(1) of this section with respect to a liquid multivitamin preparation which does not include folic acid, and the term "multivitamin" shall not be used to describe a product which fails to provide all of the minerals identified as "mandatory," for the group(s) for which the supplement is offered, in the table in paragraph (d)(1) of this section.

(3) The phrases used to designate the group(s) for which a dietary supplement is intended shall be as follows:

(i) "For infants."

(ii) "For children under 4 years of age."

(iii) "For adults and children 4 or more years of age."

(iv) "For pregnant or lactating women."

(v) If, pursuant to section 411(a)(1) of the act and paragraph (e)(1) of this section, a dietary supplement does not comply with the formulation and potency criteria established in paragraphs (b) and (c) of this section, the supplement may not be offered for any of the groups

identified in paragraph (h)(3) (i) through (iv) because the exemption from formulation and potency restrictions authorized by section 411 (a)(1) of the act and paragraph (e)(1) of this section does not apply to preparations offered for use by persons under 12 years of age or by pregnant or lactating women. Such a preparation shall accurately identify the group for which it is offered, e.g., "For adults" or "For persons 12 years of age or older, other than pregnant or lactating women."

(i) *Format for listing vitamins and minerals.* (1) Immediately following the name of the dietary supplement (i.e., the term descriptive of the vitamin and/or mineral composition of the product together with the phrase or phrases designating the group(s) for which the supplement is intended, as required by paragraph (h) of this section) on the principal display panel, or on the information panel pursuant to § 1.8d of this chapter if insufficient space is available on the principal display panel, the label shall bear a listing in tabular form of each of the vitamins and/or minerals supplied by the specified daily quantity of the dietary supplement, such daily quantity being specified at the top of the list. (In the event a dietary supplement is offered for more than one group, the specified daily quantity and listing of vitamins and/or minerals for each group shall be stated separately on the label.) The vitamins and/or minerals shall be described by the names appearing in paragraph (d) of this section and shall be grouped and identified separately as "vitamins" and/or "minerals" without reference to "mandatory" or "optional." Within each category (i.e., "vitamins" and "minerals"), the vitamins or minerals shall appear in the order listed in paragraph (d) of this section. The quantity of each vitamin and/or mineral present in a specified daily quantity of the dietary supplement shall be stated as a part of this list and expressed in percentage of the U.S. RDA for each group for which the supplement is offered. The quantity of each vitamin and/or mineral present in the specified daily quantity of the dietary supplement shall also appear in the tabular listing in terms of the unit of measure specified in paragraph (d)(1) of this section: *Provided*, That if the dietary supplement includes a vitamin or mineral for which no U.S. RDA has been established, the listing shall state the quantity in standard metric units of weight of each such nutrient supplied by the food when consumed in the specified quantity during a period of 1 day, accompanied by the statement "No U.S. Recommended Daily Allowance (U.S. RDA) has been established for this nutrient," or followed by an asterisk referring to another asterisk placed at the bottom of the table and followed by that statement.

(2) For determining the percentage contents of the U.S. RDA's present in the dietary supplement, the quantitative content of the following vitamins shall be calculated in terms of the following chemically identifiable reference forms:

Reference form

Vitamin	Name	Empirical formula	Molecular weight
Vitamin C.....	L-Ascorbic acid.....	C ₆ H ₈ O ₆	176.12
Folic acid.....	Pteroyl mono-L-glutamic acid.....	C ₂₀ H ₂₆ N ₄ O ₆	441.41
Thiamine.....	Thiamine chloride hydrochloride.....	C ₁₂ H ₁₇ ClN ₄ OS.HCl	337.26
Riboflavin.....	Riboflavin.....	C ₁₇ H ₂₀ N ₄ O ₆	376.37
Niacin.....	Nicotinic acid.....	C ₆ H ₅ NO ₂	123.11
Vitamin B ₆	Pyridoxine.....	C ₈ H ₉ NO ₃	169.15
Vitamin B ₁₂	Cyanocobalamin.....	C ₆₃ H ₈₈ CoN ₁₄ O ₁₄ P	1,354.40
Biotin.....	D-Biotin.....	C ₁₀ H ₁₆ N ₂ O ₃ S	244.31
Pantothenic acid.....	D-Pantothenic acid.....	C ₉ H ₁₇ NO ₆	219.23

(3) The following synonyms may be added in parentheses immediately following the name of the vitamin in the listing described in paragraph (i) (1) of this section:

Vitamin	Synonym
Vitamin C.....	Ascorbic acid.
Folic acid.....	Folacin.
Riboflavin.....	Vitamin B ₂ .
Thiamine.....	Vitamin B ₁ .

(j) *List of ingredients.* A separate list of all ingredients used in the manufacture of the product shall be included on the panel pursuant to the requirements of Part 1 of this chapter. Such list shall include the natural source or chemical form of each individual nutrient present in the dietary supplement.

(k) *Dietary supplements containing alcohol.* When a dietary supplement is in liquid form and contains alcohol, the label shall state the percent-by-volume of alcohol present.

(l) *Expiration date.* A dietary supplement containing one or more nutrients subject to deterioration below the labeled value before consumption shall bear on its outside wrapper or container, as well as on the label of its immediate container, the statement: "Expiration date _____," the blank to be filled in with a month and year. The expiration date shall be the date selected by the manufacturer, packer, or distributor of the dietary supplement on the basis of tests or other information showing that the dietary supplement, until that date, under the conditions of handling, storage, and use prescribed by directions appearing on its label, or, in the absence of such prescribed directions, under customary or usual conditions of handling, storage and use, will contain not less than the quantity of each such vitamin and/or mineral, as set forth on its label, when consumed.

(m) *Conspicuousness of labeling.* All labeling information required by this section shall appear with the conspicuous required by section 403(f) of the act and § 1.8d of this chapter. In addition, the following labeling requirements shall be met:

(1) The list of nutrients required by paragraph (i) (1) of this section shall appear in uniform type size.

(2) The synonyms permitted by paragraph (i) (3) of this section, if used, and the list of ingredients required by paragraph (j) of this section shall appear in uniform type size, and in type size no larger than that used for the list of nutrients required by paragraph (i) (1) of this section.

(n) *Certain labeling prohibitions.* Because dietary supplements are foods for special dietary use, the labels and labeling for dietary supplements are subject to the prohibitions contained in § 125.2(b) of this chapter in addition to the requirements of this section.

2. In Part 125:

a. By revising §§ 125.1, 125.2, and 125.3, to read as follows; by revoking § 125.4 and by amending § 125.5(e) by deleting the reference to § 125.4.

§ 125.1 Definitions and interpretations of terms.

The definitions and interpretations of terms contained in section 201 of the Federal Food, Drug and Cosmetic Act (hereafter "the act") shall be applicable with the following additions:

(a) "Special dietary use." (1) The term "special dietary use" as applied to food used by man means a particular use for which a food purports or is represented to be used, including but not limited to the following:

(i) Supplying a special dietary need that exists by reason of a physical, physiological, pathological, or other condition, including but not limited to the condition of disease, convalescence, pregnancy, lactation, infancy, allergic hypersensitivity to food, underweight, overweight, or the need to control the intake of sodium.

(ii) Supplying a vitamin, mineral, or other ingredient for use by man to supplement his diet by increasing the total dietary intake. (Rules applicable to the composition and labeling of dietary supplements of vitamins and minerals, including applicable exemptions, are provided by § 80.1 of this chapter.)

(iii) Supplying a special dietary need by reason of being a food for use as the sole item of the diet.

(2) The use of an artificial sweetener in a food, except when specifically and solely used for achieving a physical characteristic in the food which cannot be achieved with sugar or other nutritive sweetener, shall be considered a use for regulation of the intake of calories and available carbohydrate, or for use in the diets of diabetics and is therefore a special dietary use.

(b) *U.S. Recommended Daily Allowances (U.S. RDA's).* (1) The term "U.S. Recommended Daily Allowance (U.S. RDA)" means the following daily amounts of the following vitamins and minerals:

Vitamins and minerals ¹	Unit of measurement	Infants	Children under 4 years of age	Adults and children 4 or more years of age	Pregnant or lactating women
Vitamin A	International units	1,000	2,500	4,000	4,000
Vitamin D	do.	400	400	400	400
Vitamin E	do.	35	40	60	60
Vitamin C	Milligrams	1	2	4	8
Folic acid	do.	.5	.7	1.8	1.7
Thiamine	do.	.6	.8	1.7	2.0
Riboflavin	do.	8	9	20	20
Niacin	do.	.4	.7	2.0	2.8
Vitamin B ₆	do.	2	3	6	8
Vitamin B ₁₂	Micrograms	.05	.15	.30	.30
Biotin	Milligrams	3	6	10	10
Pantothenic acid	do.	.6	.8	1.0	1.3
Calcium	Grams	5	8	1.0	1.3
Phosphorus	do.	45	70	150	150
Iodine	Micrograms	15	10	18	18
Iron	Milligrams	70	200	400	450
Magnesium	do.	.8	1.0	2.0	2.0
Copper	do.	8	8	16	16
Zinc	do.				

with § 1.9 of this chapter. Such statement shall show the presence or absence of any substance, any alteration of the quantity or character of any constituent, and any other special dietary property of such food upon which such use is based.

(b) A food which purports or is represented to be a food for special dietary use shall be deemed to be misbranded under sections 201(n) and 403 (a) and (j) of the act if its labeling bears any statement, vignette, or other printed or graphic matter that represents, suggests, or implies:

(1) That the food, because of the presence or absence of certain vitamins and/or minerals, is adequate or effective in the prevention, cure, mitigation, or treatment of any disease or symptom, except that the label may state that the food is a source of an essential nutrient and that this nutrient is important for good nutrition and health, and except that provision shall not apply to foods represented for use solely under medical supervision in the dietary management of specific and disorders.

(2) That a balanced diet of ordinary foods cannot supply adequate amounts of nutrients; *Provided*, That representations may be made that it is often impractical to supply the iron requirements of infants, children, and women of child-bearing age with a diet of conventional foods.

(3) That the lack of optimum quality of a food, by reason of the soil on which that food is grown, is or may be responsible for an inadequacy or deficiency in the quality of the daily diet.

(4) That the storage, transportation, processing, or cooking of a food is or may be responsible for an inadequacy or deficiency in the quality of the daily diet.

(5) That the food has dietary properties when such properties are of no significant value or need in human nutrition. Except as provided in § 80.1(e) of this chapter, ingredients or products such as rutin, other bioflavonoids, para-aminobenzoic acid, and similar substances which have in the past been represented as having nutritional properties but which have not been shown to be essential to human nutrition may not be combined with vitamins and/or minerals, added to food labeled in accordance with this section, or otherwise used or represented in any way which states or implies nutritional benefit. Ingredients or products of this type may be marketed as individual products or mixtures thereof; *Provided*, That the possibility of nutritional, dietary, or therapeutic value is not stated or implied. Examples of false or misleading statements or implications are:

(i) Label statements to the effect that need or usefulness in human nutrition has not been established

(ii) Label statements which otherwise disclaim nutritional, dietary, or therapeutic value.

(6) That a natural vitamin in a food is superior to an added or synthetic vitamin, or that there is a difference be-

¹ The following synonyms may be added in parentheses immediately following the name of the vitamin:

Vitamin A	Synonym
Vitamin C	Ascorbic acid.
Folic acid	Folicin.
Riboflavin	Vitamin B ₂
Thiamine	Vitamin B ₁

(2) The U.S. Recommended Daily Allowances (U.S. RDA's) have been derived by the Food and Drug Administration from the "Recommended Dietary Allowances," published by the Food and Nutrition Board, National Academy of Sciences/National Research Council, and are subject to amendment as more

knowledge on human nutrient requirements becomes available.

(3) For determining the percentage of the U.S. RDA present in a quantity of food, as required by § 125.3(a), the quantitative content of the following vitamins shall be calculated in terms of the following chemically identifiable reference forms:

Reference Form			
Vitamin	Name	Empirical formula	Molecular weight
Vitamin C	L-Ascorbic acid	C ₆ H ₈ O ₆	176.12
Folic acid	Pteroyl mono-L-glutamic acid	C ₂₀ H ₂₆ N ₅ O ₆	441.41
Thiamine	Thiamine chloride hydrochloride	C ₁₂ H ₁₇ ClN ₄ OS·HCl	337.24
Riboflavin	Riboflavin	C ₁₇ H ₂₀ N ₄ O ₆	376.37
Niacin	Nicotinic acid	C ₆ H ₅ NO ₂	123.11
Vitamin B ₆	Pyridoxine	C ₈ H ₉ NO	169.15
Vitamin B ₁₂	Cyanocobalamin	C ₆₃ H ₈₈ CoN ₁₄ O ₁₄ P	1,354.40
Biotin	D-Biotin	C ₁₀ H ₁₆ N ₂ O ₆ S	244.31
Pantothenic acid	D-Pantothenic acid	C ₉ H ₁₇ NO ₆	219.23

(c) In addition to the nutrients listed in paragraph (b) of this section, other vitamins and minerals recognized as essential or probably essential in human nutrition in their biologically active forms but for which no U.S. RDA's have been established are: vitamin K, choline, and the minerals chlorine, chromium, fluorine, manganese, molybdenum, nickel, potassium, selenium, silicon, sodium, tin, and vanadium.

(d) The term "artificial sweetener" means a sweetening substance not used in normal metabolism as a source of calories.

(e) The term "infant" means a person not more than 12 months of age.

(f) The term "serving" means that reasonable quantity of food suited for or practicable of consumption as part of a meal either by an adult male engaged in light physical activity, or by an infant or child when the article purports or is represented to be for infant feeding or child consumption. A label statement regarding a serving, as used in this part, shall be in terms of a convenient unit of such food or a convenient unit of measure that can be readily understood by

purchasers of such food, e.g., a serving may be expressed in terms of slices, cookies, or wafers, or in terms of ounces, fluid ounces, teaspoonfuls, tablespoonfuls, or cupfuls. A teaspoonful shall be considered to mean 5 milliliters (approximately 1/8 fluid ounce) in volume; a tablespoonful shall be considered to mean 15 milliliters (approximately 1/2 fluid ounce) in volume; and a cupful shall be considered to mean 240 milliliters (approximately 8 fluid ounces) in volume.

(g) The term "diabetic" means a person having diabetes mellitus.

§ 125.2 General label statements: dietary properties; value; placement.

(a) If a food purports or is represented to be for any special dietary use, unless covered by other regulations, the principal display panel of its label shall bear a conspicuous statement of the usefulness of the food, limited to a listing of the dietary properties upon which such use is based; *Provided, however*, That if insufficient space is available on the principal display panel, the information panel may be used pursuant to § 1.8(d) of this chapter, if such use is consistent

tween vitamins naturally present and those that have been added.

§ 125.3 Label statements relating to vitamins and minerals.

(a) *Vitamins and minerals for which U.S. RDA's are established.* If a food purports or is represented to be for special dietary use because of vitamin or mineral properties for which U.S. RDA's have been established, the label shall bear a statement of the percentage of the U.S. RDA of such vitamins and minerals, as set forth in § 125.1(b), supplied by such food when consumed in a specified quantity during a period of 1 day. The quantity specified shall be a reasonable quantity suitable for and practicable of consumption within 1 day. The order in which the nutrients appear on the label shall be the order in § 125.1(b), except when other regulations provide otherwise. Immediately preceding the declaration of vitamin and mineral content, the following heading shall be stated, "Percentage of U.S. Recommended Daily Allowances (U.S. RDA)." If such purported or represented special dietary use is for persons within more than one group for which U.S. RDA's are established, such statement shall include the percentage for each group. When the percentage of the U.S. RDA is a whole number and a fraction or a whole number and a decimal, it shall be expressed as the whole number dis-

regarding the fraction or decimal. The total quantity of vitamins or minerals in a food shall be no less than the amount declared, and no more than a reasonable amount above the declared quantity. Reasonable variations caused by heat, light, oxidation, storage, transportation, or unavoidable deviations in good manufacturing practice are recognized.

(b) *Vitamins and minerals for which no U.S. RDA's are established.* If a food purports or is represented to be for special dietary use because of the presence of a vitamin or mineral for which no U.S. RDA has been established, the quantity of each such nutrient (in the order listed in § 125.1(c), except when other regulations provide otherwise) supplied by the food when consumed in a specified quantity during a period of 1 day shall be stated on the label in standard metric units of weight followed by the statement "No U.S. Recommended Daily Allowance (U.S. RDA) has been established for this nutrient" or by an asterisk referring to another asterisk at the bottom of the table and followed by that statement. The quantity of consumption specified shall be a reasonable quantity suitable for and practicable of consumption within 1 day.

(c) *Applicability.* When paragraphs (a) and (b) of this section are both applicable: information required by paragraph (b) with respect to vitamins shall follow immediately after information re-

quired by paragraph (a) with respect to vitamins; information required by paragraph (b) with respect to minerals shall follow immediately after information required by paragraph (a) with respect to vitamins; and the quantity of consumption specified pursuant to each paragraph shall be the same.

(d) *Iodized salt.* The requirements of this section shall not apply to iodized salt when the declared content of the iodine compound in the salt is equivalent to 0.0 percent by weight iodine.

§ 125.4 [Revoked]

b. By revoking § 125.4.

§ 125.5 [Amended]

c. In § 125.5 by deleting the reference to "125.4" in paragraph (c).

Effective date. Voluntary compliance with these regulations may begin October 19, 1976 and all products initially introduced into interstate commerce on or after January 1, 1978, shall fully comply (Secs. 201(n), 401, 403 (a) and (j), 411, 7 (a) and (e), 52 Stat. 1041, 1046-1048, 1070 Stat. 919, 90 Stat. 410-411 (21 U.S.C. 3 (n), 341, 343 (a) and (j), 350, 371 (a) and (e)).)

Dated: October 12, 1976.

A. M. SCHMIDT,
Commissioner of Food and Drugs.
[FR Dec.76-30404 Filed 10-18-76; 6:45 am]

RULES AND REGULATIONS

ately on April 19, 1977. Before issuing a final regulation, the Commission will consider any timely comments received concerning this interim amendment. This interim amendment shall in no other way abrogate or restrict the special packaging standard covering other preparations containing aspirin.

Interested persons are invited to submit, on or before May 19, 1977 written comments regarding this interim amendment. Comments received after this date will be considered if practicable. Comments and any accompanying data or material should be submitted preferably in five copies, addressed to the Secretary, Consumer Product Safety Commission, Washington, D.C. 20207. Comments may be accompanied by a memorandum or brief in support thereof. Received comments and accompanying data may be seen in the Office of the Secretary, 1111 18th Street, NW., Third floor, Washington, D.C. 20207.

Dated: April 11, 1977.

SADYE E. DUNN,
Secretary, Consumer Product
Safety Commission.

[FR Doc. 77-11241 Filed 4-18-77; 8:45 am]

Title 18—Conservation of Power and Water Resources

CHAPTER I—FEDERAL POWER COMMISSION

[Docket No. RM 74-16]

PART 260—STATEMENTS AND REPORTS (SCHEDULES)

Order Reopening Record and Providing for Additional Evidence; Correction

AGENCY: Federal Power Commission.

ACTION: Correction.

SUMMARY: This document corrects an order that appeared on Page 9017 in the FEDERAL REGISTER of February 14, 1977 (FR Doc. 77-4263).

EFFECTIVE DATE: April 19, 1977.

FOR FURTHER INFORMATION CONTACT:

Kim Clark, 202-275-4331, Office of General Counsel.

The following correction is made:
Page 9017, Paragraph 3, line 9: Change August 15, 1975, to August 18, 1975.

KENNETH F. PLUMS,
Secretary.

[FR Doc. 77-11107 Filed 4-18-77; 8:45 am]

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER B—FOOD FOR HUMAN CONSUMPTION

[Docket No. 75N-0117]

PART 105—FOODS FOR SPECIAL DIETARY USE

Vitamin and Mineral Products; Action on Petitions for Reconsideration of Final Regulations

AGENCY: Food and Drug Administration, HEW.

ACTION: Rule.

SUMMARY: In response to petitions for reconsideration, the Food and Drug Administration (FDA) is generally reaffirming its vitamin and mineral regulations published in the FEDERAL REGISTER of October 19, 1976 (41 FR 46156). However, certain regulations are revised to provide in general terms that vitamin and mineral preparations newly authorized by Congress, for which particular names have not been established by regulation, shall bear "an appropriate descriptive term."

EFFECTIVE DATE: January 1, 1978, for all products initially introduced into interstate commerce on or after this date.

Voluntary compliance: immediately.

FOR FURTHER INFORMATION CONTACT:

John E. Vanderveen, Bureau of Foods (HFF-260), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, D.C. 20204, 202-245-1064.

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of October 19, 1976 (41 FR 46156), FDA issued revised final regulations governing the labeling and composition of dietary supplements and other foods that purport or are represented to be for special dietary use because of their vitamin and/or mineral properties. The regulations were issued pursuant to remand directions by the United States Court of Appeals for the Second Circuit, "National Nutritional Foods Assn. v. FDA," 504 F.2d 761 (2d Cir. 1974), and the 1976 vitamin and mineral amendments to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350). The Food and Drug Administration provided that voluntary compliance with the regulations might begin immediately and that all products initially introduced into interstate commerce on or after January 1, 1978, shall fully comply.

Subchapter B of Chapter I of Title 21, which contains all FDA regulations for food for human consumption, was reorganized and republished in the FEDERAL REGISTER of March 15, 1977 (42 FR 14302). Former Parts 80 and 125, under which the regulations of October 19, 1976, were issued, were transferred to Part 105—Foods for Special Dietary Use. For the convenience of the reader, the former designation of the reclassified section numbers used throughout this document are set forth as follows:

New section No.:	Old section No.:
101.9	1.1
105.3	125.1
105.60	125.2
105.62	125.8
105.65	125.5
105.67	125.6
105.69	125.9
105.77	125.3
105.79	125.7
105.85	60.1

The Commissioner of Food and Drug has received two petitions for reconsideration and one request for confirmation of interpretation filed in response to the October 19, 1976 regulations:

1. A letter, dated November 12, 1976 from Miles H. Robinson, M.D., "for himself, Federation of Homemakers, Mary Hill, Ralph P. Glaser, Karl F. Lutz, Janie A. Meeter, and National Health Federation" stating that they "cannot agree" with the Commissioner's judgment that the cross-examination of Dr. Alfred E. Harper at the reopened administrative hearing, November 10-17, 1976 did not "impugn the U.S. FDA's" (recommended daily allowances); and

2. A petition, dated November 30, 1976 from the National Nutritional Foods Association, the National Association of Pharmaceutical Manufacturers, and the Solgar Co., Inc., asking that the Commissioner reconsider the propriety of amending the regulation to comply with the 1976 vitamin and mineral amendments to the Federal Food, Drug, and Cosmetic Act without first issuing a proposal providing an opportunity for a formal administrative hearing. The petition asked that the Commissioner withdraw the regulation until such procedural steps are undertaken.

3. A letter, dated November 22, 1976 from Tillie Lewis Foods, Inc., asked for confirmation of its interpretation that its products are not subject to § 105.3.

Copies of these documents are on file with the Hearing Clerk, FDA, and they are available for public inspection.

The Commissioner has reconsidered the regulations, and he concludes that certain changes should be made. The petitions and request for confirmation received and the Commissioner's responses are discussed below.

LETTER FROM DR. ROBINSON

Dr. Robinson's letter lists eight reasons for his belief that the cross-examination of Dr. Harper at the reopened administrative hearing, held November 10-17, 1975, substantially impugned the validity of the U.S. RDA's.

The Commissioner has already addressed the issues raised by the letter. (See the Commissioner's discussion and rulings on exceptions filed by Dr. Robinson and others who responded to the report and recommended order of the Administrative Law Judge, published in the *FEDERAL REGISTER* of October 19, 1976 (41 FR 46158-46166).) Except for one issue, the Commissioner concludes that his discussion and rulings in the *FEDERAL REGISTER* of October 19, 1976 are reaffirmed without further discussion.

Dr. Robinson's letter of November 12, 1976, states:

We believe the cross-examination, among other things, showed . . . (3) improper reliance on current nutrient content of the U.S. food supply, emphasized by substantial evidence from the U.S. Department of Agriculture published shortly after the cross-examination and not available theretofore which we believe was improperly denied admission into evidence . . .

The "evidence from the U.S. Department of Agriculture" consists of an article by W. A. Gortner, entitled "Nutrition in the United States, 1900 to 1974," published in "Cancer Research" (November 1975). In the *FEDERAL REGISTER* of October 19, 1976 (41 FR 46163), the Commissioner ruled:

9. "Motion to Receive in Evidence U.S.D.A. Article on Nutrient Availability". On March 30, 1976, after the hearing was completed, Dr. Miles H. Robinson, et al., filed with the Commissioner a "Motion to Receive in Evidence U.S.D.A. Article on Nutrient Availability." This article was never mentioned during the reopened hearing. This article should have been produced at the hearing so that a proper foundation could have been made as to its authenticity, reliability, and relevancy. Accordingly, this motion is denied.

Although it appears from the date of the periodical (November 1975) that the article was available during the reopened hearing (held November 10-17, 1975) and that Dr. Robinson should have produced the article at the hearing if he wished to rely on it, the Commissioner has decided not to stand on procedural grounds but to receive the article into the record. A copy of the article is on file with the Hearing Clerk, FDA, and is attached to Dr. Robinson's motion of March 30, 1976.

The Commissioner has considered this article, and he concludes that it does not show that the U.S. RDA's reflect Dr. Robinson's assertion of "improper reliance on current nutrient content of the U.S. food supply."

As stated in his motion of March 20, Dr. Robinson's thesis is that the Food and Nutrition Board of the National Academy of Sciences-National Research Council (NAS/NRC) has been "covertly looking over its self-interested shoulder at the ceiling of available nutrients in the U.S. food supply; and so far as it dared, the Board has tailored its RDA's to keep them from rising above that ceiling" (Motion p. 3).

However, Dr. Robinson's motion of March 20 states that the Gortner article shows that "the food supply is below the RDA for calcium (95%) and magnesium (87%), and uncomfortably close for iron (102%), B₆ (114%) and niacin (117%)" (Motion p. 5; emphasis in original). The Commissioner concludes that, if relevant at all, such statistics militate against Dr. Robinson's arguments that the Food and Nutrition Board has pursued a result-oriented policy of setting its RDA's at a level so low that the food supply of the United States will appear to provide an ample surplus of nutrients. For, to use Dr. Robinson's figures, if the Board really were pursuing a result-oriented policy of making the United States food supply "look good," it would hardly have adopted figures for calcium and magnesium that might cause the food supply to appear deficient in those nutrients, nor would it have adopted figures for iron, vitamin B₆, and niacin so "uncomfortably close" (to use Dr. Robinson's words) to the levels provided by the food supply.

Furthermore, contrary to Dr. Robinson's assertions that the Board was oriented toward low levels, to cause the food supply to appear to be nutritious, Dr. Harper explained during the reopened hearing that the RDA's were set to exceed people's needs and that "you may well expect half the population to eat less than the RDA and still meet their needs completely" (Tr. 32073).

The Commissioner notes that a fundamental assumption of Dr. Robinson's is that lower RDA's are in the interest of the food industry. This assumption is doubtful—higher RDA's might favor certain segments of the industry. For example, higher RDA's might suggest to some consumers that the food supply is inadequate and that more vitamins and minerals should be consumed. Thus, manufacturers and sellers of vitamins and minerals and ingredients used as sources of vitamins and minerals might find increased markets for their products if RDA's were raised. Also, foods recognized as good natural sources of particular vitamins and minerals might increase their sales if RDA's for vitamins and minerals were raised. In any event, the Commissioner finds no convincing arguments or data to support Dr. Robinson's allegations that the Board was guided by the purpose of satisfying interests of the "food industry."

The Commissioner concludes that the cross-examination of Dr. Harper at the reopened administrative hearing confirms that the methodology use in the de-

velopment of the NAS/NRC RDA's was appropriate and that, to the extent that the Committee on Dietary Allowances of the Food and Nutrition Board took into consideration the nutrient content of the United States food supply, it did so in accordance with sound scientific principles. The Commissioner reaffirms his discussion of "Allegations of improper reliance on the 'food supply'" published in the *FEDERAL REGISTER* of October 19, 1976 (41 FR 46159-46160).

NNFA PETITION

The petition by the National Nutritional Foods Association and others ("NNFA petition") raises a legal issue that was not extensively addressed in the preamble to the October 19, 1976 regulations, and accordingly the Commissioner takes this opportunity to explain more fully why he has concluded that the FDA vitamin and mineral regulations, §§ 105.3, 105.60, 105.77, and 105.85 (21 CFR 105.3, 105.60, 105.77, and 105.85), may properly be amended in response to requirements of the 1976 vitamin and mineral amendments to the Federal Food, Drug, and Cosmetic Act without FDA first issuing a proposal and providing an opportunity for a formal administrative hearing.

On April 22, 1976, the President signed the new legislation that amended the Federal Food, Drug, and Cosmetic Act inter alia to restrict FDA authority to limit the inclusion of ingredients and maximum potency of vitamins and minerals in dietary supplements (in tablet, capsule, droplet, or other form not resembling "conventional" foods) that are offered for use by adults, other than pregnant or lactating women, and are recognized as safe (Pub. L. No. 94-278, Title V, sections 501-502, 50 Stat. 410-413; codified in part, 21 U.S.C. 350). This new legislation was discussed in detail in the Commissioner's *Federal Register* document of October 19, 1976. (See "1976 Amendments to Federal Food, Drug, and Cosmetic Act" (41 FR 46169-46170).)

Congress specifically provided that any existing FDA regulations that were inconsistent with the new vitamin and mineral legislation must be amended:

The Secretary of Health, Education, and Welfare shall amend any regulation promulgated under the Federal Food, Drug, and Cosmetic Act which is inconsistent with section 411 of such Act (as added by subsection [501](a)) and such amendments shall be promulgated in accordance with section 553 of title 5, United States Code, (Act of April 22, 1976, Pub. L. No. 94-278, Title V, section 501(b), 90 Stat. 411 (21 U.S.C. 350 note).) (Note.—Section 501(a) of Title V, to which section 501(b) refers, adds a new section 411 (codified as 21 U.S.C. 350) to the Federal Food, Drug, and Cosmetic Act, and it is this new section of the act on which the changes in the regulations, discussed below, were premised.)

Thus Congress provided that any changes in FDA's vitamin and mineral regulations needed for consistency with the new legislation should be promulgated pursuant to U.S.C. 553, the general provision of the Administrative Pro-

cedure Act governing "Rule making." The Commissioner believes that this provision authorizes him to amend the FDA vitamin and mineral regulations to coincide with the provisions of the new vitamin and mineral amendments to the Federal Food, Drug, and Cosmetic Act without prior notice of proposed rule making and public procedure because U.S.C. 553(b)(3) specifically provides that notice and public procedure are not required "when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." As discussed below, the Commissioner specifically concludes in this case that notice and public procedure would be impracticable, unnecessary, and contrary to the public interest.

It should be noted here that only a small portion of the text of the regulations published in the *Federal Register* of October 19 consists of revisions prompted by the new vitamin and mineral amendments to the Federal Food, Drug, and Cosmetic Act; most of the text of the regulations consists either of republication of provisions upheld by the Second Circuit or of revisions resulting from the remand directions of the Second Circuit.

The provisions of the vitamin and mineral regulations published in the *Federal Register* of October 19 that were prompted by the new legislation are as follows:

1. *Revision of § 105.3(a).* This paragraph defines the term "special dietary use." It was revised to incorporate verbatim the definition of "special dietary use" provided by Congress in new section 411(c)(3) of the act (21 U.S.C. 350(c)(3)). The Commissioner concludes that no useful purpose would be served in notice and public procedure regarding inclusion of a definition established by Congress. The Commissioner concludes that notice and public procedure regarding revision of § 105.3(a) would be "impracticable" and "unnecessary" within the meaning of 5 U.S.C. 553(b)(3). (Section 125.1(a) had previously defined "special dietary use" in slightly different terms—see the *Federal Register* of August 2, 1973 (38 FR 20717).)

2. *New § 105.85(e).* This paragraph provides that pursuant to section 411(a)(1) of the act (21 U.S.C. 350(a)(1)), the limitations established by the FDA vitamin and mineral regulations regarding inclusion of vitamins, minerals, and other ingredients and maximum limits on potency shall not apply to a food for special dietary use that is or contains any vitamin or mineral and complies with the following criteria:

(i) The preparation is intended for ingestion in tablet, capsule, or liquid form, or, if not intended for ingestion in such a form, does not simulate and is not represented as conventional food and is not represented for use as a sole item of a meal or of the diet; and

(ii) The preparation is not represented for use by individuals in treatment or management of specific diseases or disorders, by children, or by pregnant or lactating women.

This new regulation only incorporates exemption from formulation restriction for certain adult preparations—an exemption explicitly mandated by the legislation. That legislation provides the Secretary of Health, Education, and Welfare (Secretary) "may not establish, under section 201(n), 401, or 403 (of the Federal Food, Drug, and Cosmetic Act, i.e., 21 U.S.C. 321(n), 341, and 343, the statutory sections upon which FDA's vitamin and mineral regulations were premised), maximum limits on the potency of any synthetic or natural vitamin or mineral within a food to which this section applies" and that the Secretary "may not limit, under section 201 (n), 401 or 403, the combination or number of any synthetic or natural—(i) vitamin, (ii) mineral, or (iii) other ingredient of food, within a food to which this section applies" (21 U.S.C. 350(a)(1)(A) and (C)). The language of the regulation describing the special dietary food preparations to which the exemption applies, quoted above, is taken substantially verbatim from the new legislation (21 U.S.C. 350(a)(2) and (c)(1)).

There would be no useful purpose in engaging in notice and public procedure in adopting this section of the regulations. Congress has effectively exempted certain vitamin and mineral preparations from FDA regulations establishing formulation restrictions, and FDA has amended its regulations for consistency with the statutory exemption. Accordingly, the Commissioner concludes that notice and public procedure regarding § 105.85(e) would be "impracticable" and "unnecessary" within the meaning of 5 U.S.C. 553(b)(3).

3. *Revision of § 105.60(b)(5).* This paragraph generally has the effect of prohibiting the combination with vitamins and/or minerals of "ingredients or products such as rutin, other bioflavonoids, para-aminobenzoic acid, and similar substances which have in the past been represented as having nutritional properties but which have not been shown to be essential to human nutrition." The provision was upheld by the Court of Appeals (504 F.2d at 804-805).

However, the new vitamin and mineral amendments to the Federal Food, Drug, and Cosmetic Act provide that, with respect to vitamin and mineral preparations subject to the new legislation, the Secretary "may not limit . . . the combination or number of any synthetic or natural—(i) vitamin, (ii) mineral, or (iii) other ingredient of food . . ." (21 U.S.C. 350(a)(1)(C)). As discussed above, the Commissioner added § 105.85(e) to incorporate the new statutory exemption. Section 105.60(b)(5) was amended simply to cross-reference the exemption recognized in § 105.85(e), by adding the introductory clause "Except as provided in § 105.85(e) of this chapter . . ."

No useful purpose would be served in notice and public procedure regarding adoption of this amendment to § 105.60(b)(5). Congress has directed that, with respect to the food products to which the new vitamin and mineral legislation applies, FDA may not limit the combination or number of ingredients. To comply with this statutory command, the Commissioner amended the vitamin and mineral regulations in § 105.85(e) so that they no longer limit the combination or number of ingredients in foods to which the new legislation applies. Accordingly, regarding the amendment to § 105.60(b)(5), which simply cross-references the exemption recognized by § 105.85(e) pursuant to the new legislation, the Commissioner concludes that notice and public procedure would be "impracticable" and "unnecessary" within the meaning of 5 U.S.C. 553(b)(3).

4. *Deletion of § 125.1(h) (would have appeared in § 105.3(h) if it had not been deleted before recodification).* This paragraph had provided that, with certain exceptions, "Any product containing more than the upper limit of the U.S. RDA per serving (or, where appropriate, per daily recommended quantity) of a vitamin or mineral as specified in § 80.1(f)(1) (recodified as § 105.85(f)(1)) of this chapter is a drug . . ." (38 FR 20717; August 2, 1973).

The new vitamin and mineral legislation specifically provides that the Secretary "may not classify any natural or synthetic vitamin or mineral (or combination thereof) as a drug solely because it exceeds the level of potency which the Secretary determines is nutritionally rational or useful" (21 U.S.C. 350(a)(1)(B)). Section 125.1(h) had the effect of classifying a vitamin or mineral preparation as a drug solely because it exceeded the level of potency determined by the Secretary (FDA) to be nutritionally rational or useful, i.e., if it exceeded the upper limit of the U.S. RDA as then specified in § 80.1(f)(1) (recodified as § 105.85(f)(1)). Accordingly, to comply with the new legislation (21 U.S.C. 350(a)(1)(B)), it was necessary for the Commissioner to delete § 125.1(h) from the regulations.

Furthermore, as discussed in the preamble to the October 19, 1975 regulations (41 FR 46169) the deletion of § 125.1(h) was independently required by the remand directions of the Second Circuit. The Court of Appeals specifically ruled that § 125.1(h) was invalid, and thus its deletion was required even in the absence of the new vitamin and mineral legislation (504 F.2d 789).

No useful purpose would have been served in further notice and public procedure regarding deletion of § 125.1(h)—it was effectively required both by the Court of Appeals and by Congress. Accordingly, the Commissioner concluded that further notice and public procedure regarding deletion of § 125.1(h) were "impracticable" and "unnecessary" within the meaning of 5 U.S.C. 553(b)(3).

5. New § 105.85(h) (2) (vii) and (3) (v). The vitamin and mineral regulations generally provide that the name of a dietary supplement shall consist of a term descriptive of the vitamin and/or mineral composition of the product, e.g., "multivitamin and multimineral supplement", together with a phrase or phrases designating the group(s) for which the supplement is intended, e.g., "for children under 4 years of age". (See § 105.85(h) (1).) Section 105.85(h) (2) specifies the terms to be used to describe the composition of certain formulations, and § 105.85(h) (3) specifies the phrases to be used to designate certain groups for which a supplement may be intended. The Second Circuit took specific note of § 105.85(h) (then codified at § 89.1(h)) (see 504 F.2d 770) and made no requirements for any changes in its remand directions.

The new vitamin and mineral legislation, however, has the effect of permitting sale of certain dietary supplement preparations for adults (other than pregnant or lactating women) that FDA regulations formerly had proscribed—preparations containing more than 150 percent of the U.S. RDA of included vitamins and minerals, preparations containing ingredients not shown to have nutritional usefulness, and multivitamin preparations containing less than the full spectrum of vitamins and/or minerals classified by FDA as "mandatory". As discussed above, § 105.85(e) was added to the regulations to comply with the statutory command that FDA not prohibit such preparations. It therefore became necessary also to amend the regulations to provide for appropriate nomenclature for these preparations that previously had not been authorized for sale; and accordingly, in the *FEDERAL REGISTER* of October 19, 1976 (41 FR 46173), the Commissioner added new paragraphs (h) (2) (vii) and (h) (3) (v) to § 105.85.

These new paragraphs were intended to provide, in general terms, for appropriately descriptive labeling for the vitamin and mineral preparations newly authorized by Congress. They provided that such a preparation "shall bear a term that is accurately descriptive of its vitamin and/or mineral composition" (§ 105.85(h) (2) (vii)) and that such a preparation "shall accurately identify the group for which it is offered" (§ 105.85(h) (3) (v)).

Upon reconsideration, the Commissioner has determined that § 105.85(h) (2) (vii) should be revised. The Commissioner is revising § 105.85(h) (2) (vii) to provide simply that a preparation which, pursuant to the new legislation, does not comply with any of the formulation criteria previously established for particular products, shall bear as a part of the name "an appropriately descriptive term." If the Commissioner concludes that more definite rules of nomenclature are needed for the products recently authorized by Congress, he will issue appropriate proposals.

Section 105.85(h) (2) (vii) continues to provide, however, that, with one specified

exception, the terms "multivitamin" and "multimineral" shall not be used to describe a product that fails to provide all the "mandatory" vitamins and minerals established by § 105.85(d). The Commissioner concludes that this provision is necessary as a matter of law to prevent consumer confusion. The regulations already provide that products labeled as "multivitamin" and/or "multimineral" preparations must contain certain "mandatory" vitamins and/or minerals that have been recognized as essential to human nutrition (§ 105.85(h) (2) (i)-(iv)). Although Congress has now authorized multivitamin supplements containing less than the full spectrum of needed vitamins and/or minerals, it would not be proper to allow such preparations to be labeled as "multivitamin" or "multimineral" preparations because use of these particular terms would cause confusion with the full-spectrum "multivitamin" and/or "multimineral" preparations, in violation of 21 U.S.C. 343(g), and would also be misleading, in violation of 21 U.S.C. 343(a). As the Court of Appeals stated with respect to a vitamin or mineral preparation that does not contain the full range of needed nutrients: "Obviously, the manufacturer of a product in this latter category could be prohibited from using the words 'multivitamin' and/or 'multimineral.'" (504 F.2d 785, fn. 29.)

The Commissioner has concluded that § 105.85(h) (3) (v) should not be revised. This paragraph simply requires that a subject preparation " . . . accurately identify the group for which it is offered, e.g., 'For adults' . . ." Such a requirement is obviously reasonable, and the Commissioner believes that no one would oppose the provision. In any event, such a provision is necessary to avoid misleading labeling—dietary supplements are used by different population groups with distinct nutritional requirements, for example, infants, pregnant or lactating women, adults (see Finding of Fact No. 14 in the preamble to the dietary supplement regulations published in the *FEDERAL REGISTER* of August 2, 1973 (38 FR 20725)), and a dietary supplement that failed to describe the group for which it is offered would be misbranded because its labeling would be misleading for failure to reveal a material fact within the meaning of 21 U.S.C. 321(n) and 343(a). Congress specifically stated, in passing the new vitamin and mineral legislation, that although it intended to authorize the sale of certain safe vitamin and mineral preparations previously proscribed by FDA, it was not authorizing the use of misleading labeling for such preparations (H.R. Rep. No. 94-1005, 94th Cong., 2d Sess. 29 (April 2, 1976); S. Rep. No. 94-743, 94th Cong., 2d Sess. 29 (April 8, 1975)).

The Commissioner concludes that no useful purpose would be served in notice and public procedure regarding § 105.85(h) (2) (vii) and (3) (v), which concern nomenclature for the vitamin and mineral preparations newly authorized by Congress. These amendments simply provide for basic nomenclature with respect

to the preparations newly authorized by Congress, nomenclature which is necessary to avoid misleading labeling and which is consistent with the general pattern of nomenclature for dietary supplements as previously established by § 105.85(h) (formerly codified as § 89.1(h)) after a 2-year formal administrative hearing and sustained on judicial review (504 F.2d 770, 786). Accordingly, he concludes that notice and public procedure were "impracticable" and "unnecessary" within the meaning of 5 U.S.C. 553(b) (2).

6. Section 105.85 (c) (3), (b), (c). These paragraphs were amended to cross-reference new § 105.85(e), which is discussed above. Notice and public procedure on cross-referencing would be a pointless waste of time—"impracticable" and "unnecessary" within the meaning of 5 U.S.C. 553(b) (2).

In summary, these revisions of the regulations essentially represent FDA's non-discretionary compliance with specific restrictions upon its authority imposed by Congress in the new legislation. None of the revisions raises substantial factual or policy issues for resolution by FDA for which notice and public procedure would have been useful. Congress, in promulgating the new legislation, resolved the relevant factual and policy issues by legislative fiat.

The Commissioner disagrees with the assertion in the National Nutritional Foods Association petition that, with respect to changes in the regulations resulting from the new vitamin and mineral legislation, the Commissioner should have followed the procedures described in section 701(e) of the act (21 U.S.C. 371(e)). That section, if applicable, would require a protracted formal rulemaking proceeding before FDA could promulgate changes required by Congress.

Ordinarily, standards of identity and special dietary food regulations are promulgated pursuant to 21 U.S.C. 341 and 343(j), and subject to the rulemaking procedures of 21 U.S.C. 371(e). (See 21 U.S.C. 371(e) (1).) Indeed, all the provisions of §§ 105.3, 105.60, 105.67 and 105.85, other than the few changes, discussed above, mandated by the new vitamin and mineral legislation, were the subject of full 21 U.S.C. 371(e) procedures including lengthy formal administrative hearings held in 1968-1970 and, pursuant to the remand directions of the Court of Appeals, reopened in 1975. (For a description of the 14-year process of rulemaking supporting the dietary supplement regulations published in the *FEDERAL REGISTER* of October 19, 1975, see (1) The sections entitled "History" in the preambles to the tentative regulations published in the *FEDERAL REGISTER* of January 19, 1973 (38 FR 2143, 2150); (2) the preambles to the final regulations published in the *FEDERAL REGISTER* of August 2, 1973 (38 FR 20703, 20709) (subsequently stayed by the Court of Appeals); (3) the preamble to the *FEDERAL REGISTER* document of May 23, 1975 (41 FR 23244) instituting further rulemaking pursuant to the remand directions of the Court of Appeals; and (4) the section on

titled "History" in the preamble to the revised final regulations published in the FEDERAL REGISTER of October 19, 1976 (41 FR 46156).)

Congress specifically provided in the new vitamin and mineral legislation that:

The Secretary of Health, Education, and Welfare shall amend any regulation promulgated under the Federal Food, Drug, and Cosmetic Act which is inconsistent with the new vitamin and mineral legislation and such amendments shall be promulgated in accordance with section 553 of title 5, United States Code. (Act of April 22, 1976, Pub. L. 94-278, Title V, section 501(b), 90 Stat. 411 (21 U.S.C. 350 note).)

If Congress had intended that changes made to conform FDA regulations with the new legislation be accomplished pursuant to the formal administrative procedures set forth in 21 U.S.C. 371(e), there would have been no purpose in mentioning 5 U.S.C. 553 instead of 21 U.S.C. 371(e) in the new legislation. The logical inference is that Congress, recognizing that there was no useful purpose in holding further rulemaking proceedings, including another formal administrative hearing, for the essentially ministerial purpose of amending FDA regulations for consistency with the explicit provisions of the new vitamin and mineral legislation, instead intended that amendment of FDA regulations for consistency with the new legislation could be accomplished in a manner consistent with 5 U.S.C. 553. In short, notice and public procedure, being unnecessary and impracticable for ministerial execution of explicit Congressional commands, were not required (5 U.S.C. 553(b)(3)).

Furthermore, the amendments to the vitamin and mineral regulations resulting from the new legislation are not amendments under 21 U.S.C. 341 and 343 (j); the amendments are under 21 U.S.C. 350. 21 U.S.C. 350 is not one of the sections of the Federal Food, Drug, and Cosmetic Act listed in 21 U.S.C. 371(e) (1), and thus the procedural requirements of 21 U.S.C. 371(e) are not applicable to the few amendments to the vitamin and mineral regulations resulting from the new legislation.

If a new 21 U.S.C. 371(e) proceeding were required to implement the requirements of Congress, the effective date of the new regulations would be substantially further delayed. The Commissioner recognizes that certain interests would benefit from such delays, but he believes that such delays would clearly be contrary to the public interest.

TILLIE LEWIS FOODS, INC.: REQUEST FOR CONFIRMATION OF INTERPRETATION

In addition to the two petitions for reconsideration, a canner of fruits and vegetables (Tillie Lewis Foods, Inc.) filed a letter requesting confirmation of its interpretation of the status of canned fruits and vegetables that naturally provide per serving more than 50 percent of the U.S. RDA of a vitamin or mineral but are not represented as dietary supplements. The Commissioner advises that, consistent with the company's

stated assumption, such a canned fruit or vegetable, e.g., canned carrots, is not subject to § 105.85. Such a product is not within the scope of § 105.85(a)(1)—no exemption is needed in § 105.85(a)(2) to make it clear that § 105.85 is not applicable in this case. Ordinary nutrition claims for such a product are covered by nutrition labeling regulations under § 101.9 (21 CFR 101.9).

In promulgating the final regulations of October 19, 1976, the Commissioner endeavored to comply conscientiously with the remand directions of the Court of Appeals. Furthermore, obeying explicit new statutory commands, the Commissioner at the same time also revised the regulations to be consistent with the new vitamin and mineral legislation; for example, the regulations no longer purport to limit the inclusion of ingredients or maximum potency of vitamins and minerals in preparation subject to the new legislation. Two petitions for reconsideration and a request for confirmation of interpretation were filed with the Commissioner in response to the October 19 regulations, and he has now ruled upon these submissions, revising the regulations in one respect.

The Commissioner believes that there is no valid pretext for further litigation over the propriety of these regulations. However, if any of the petitioners for reconsideration believes that the new regulations fail to comply with the remand directions of the Court of Appeals as controlled by new requirements of Congress, the Commissioner asks that any such person seek relief from the United States Court of Appeals for the Second Circuit forthwith so that the matter can be resolved as quickly as possible. The regulation of dietary supplements has been a matter of controversy for 14 years, with almost constant activity and uncertainty in the administrative, judicial, and legislative arenas. There is need now for certainty and finality in the rules that govern this subject.

Voluntary compliance with these regulations may begin immediately, and all products initially introduced into interstate commerce on or after January 1, 1978, shall fully comply.

Therefore, in accordance with the foregoing discussion, and under the Federal Food, Drug, and Cosmetic Act (secs. 201(n), 401, 403 (a) and (j), 411, 701 (a) and (e), 52 Stat. 1041 as amended, 1046-1048 as amended, 1055, 70 Stat. 919, 90 Stat. 410-411 (21 U.S.C. 321(n), 341, 343 (a) and (j), 350, 371 (a) and (e))), and under authority delegated to the Commissioner (21 CFR 5.1), the vitamin and mineral regulations published in the FEDERAL REGISTER of October 19, 1976 (41 FR 46156-46176), are reaffirmed, except that Part 105 is amended by revising § 105.85(h)(2)(vii) to read as follows:

§ 105.85 Dietary supplements of vitamins and minerals.

(h)
(2)

(vii) If, pursuant to section 411(a)(1) of the act and paragraph (e)(1) of this

section, the dietary supplement contains more than one vitamin or mineral but does not meet the criteria for any of the preparations identified in paragraph (h)(2)(i) through (vi) of this section, the preparation shall bear as a part of the name an appropriately descriptive term: *Provided*, That the term "multivitamin" shall not be used to describe a product that fails to provide all the vitamins identified as "mandatory" for the group(s) for which the supplement is offered, in the table in paragraph (d)(1) of this section, except as provided in the second proviso clause of paragraph (b)(1) of this section with respect to a liquid multivitamin preparation that does not include folic acid: *And provided further*, That the term "multimineral" shall not be used to describe a product that fails to provide all the minerals identified as "mandatory" for the group(s) for which the supplement is offered, in the table in paragraph (d)(1) of this section.

Effective date: Voluntary compliance with these regulations may begin immediately, and all products initially introduced into interstate commerce on or after January 1, 1978, shall fully comply.

(Secs. 201(n), 401, 403 (a), (j), 411, 701 (a), (e), 52 Stat. 1041 as amended, 1046-1048 as amended, 1055, 70 Stat. 919, 90 Stat. 410-411 (21 U.S.C. 321(n), 341, 343 (a), (j), 350, 371 (a), (e))).

Dated: April 12, 1977.

JOSEPH P. HILE,
Associate Commissioner
for Compliance.

[FR Doc.77-11240 Filed 4-18-77; 8:45 am]

Title 24—Housing and Urban Development SUBTITLE A—OFFICE OF THE SECRETARY, DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. R-77-350]

PART 16—IMPLEMENTATION OF THE PRIVACY ACT OF 1974

Final Rule

AGENCY: Department of Housing and Urban Development.

ACTION: Final rule.

SUMMARY: This document makes final an interim rule published October 8, 1976, at 41 FR 44556 permitting HUD Privacy Officers to deny access to records contained in HUD Privacy Act Records Systems when the Privacy Act provides a specific exemption.

EFFECTIVE DATE: April 12, 1977.

ADDRESS: Rules Docket Clerk, Office of the Secretary, Room 10141, Department of Housing and Urban Development, 451 7th Street S.W., Washington, D.C. 20410, 202-755-5703.

SUPPLEMENTARY INFORMATION: Public comments were solicited on the interim rule with comments to be submitted on or before November 8, 1976. No comments were received. The rule is already effective as an interim rule to avoid disclosures which might seriously